

**SOLICITATION****SECTION A - SOLICITATION/CONTRACT FORM**

Page 1 of 78 pages

1. Purchase Authority: Public Law 92-218 as amended

2. <b>Request For Proposal (RFP) Number:</b> NIH-ES-04-12	3. <b>Issue Date:</b> August 18, 2004	4. <b>Just In Time:</b> <input checked="" type="checkbox"/> NO <input type="checkbox"/> YES See Part IV Section L	5. <b>Set Aside:</b> <input checked="" type="checkbox"/> NO <input type="checkbox"/> YES See Part IV Section L
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- 6.
- TITLE:**
- STUDIES TO EVALUATE THE TOXIC AND CARCINOGENIC POTENTIAL OF TEST ARTICLES IN LABORATORY ANIMALS FOR THE NATIONAL TOXICOLOGY PROGRAM (NTP)

7. <b>ISSUED BY:</b>  Research Contracts Branch National Institute of Environmental Health Sciences National Institutes of Health 79 T.W. Alexander Dr., 4401 Research Commons  P.O. Box 12874 Research Triangle Park, North Carolina 27709	8. <b>SUBMIT OFFERS TO:</b>  See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 10 of this Solicitation.
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9. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in Attachment 10 until 3:00 pm local time on October 14, 2004. Offers will be valid for 120 days unless a different period is specified by the offeror on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043."
10. THIS SOLICITATION REQUIRES DELIVERY OF PROPOSALS TO THE OFFICIAL POINT OF RECEIPT FOR THE PURPOSE OF DETERMINING TIMELY DELIVERY AS STATED IN ATTACHMENT 10. IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HIS DESIGNEE AT THE PLACE AND TIME SPECIFIED FOR THE RESEARCH CONTRACTS BRANCH, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH HHSAR CLAUSE 352.215-70, ENTITLED, "LATE PROPOSALS, AND REVISIONS" LOCATED ON PAGE 44 OF THIS SOLICITATION.
11. Offeror must provide full name, address, TIN, and, if different, the address to which payment should be mailed.
12. FOR INFORMATION CALL: MARILYN B. WHALEY  
PHONE: (919) 541-0416  
COLLECT CALLS WILL NOT BE ACCEPTED.
13. Table of Contents on following page.

Marilyn B. Whaley  
Contracting Officer  
Research Contracts Branch  
National Institute of Environmental Health Sciences

### 13. DETAILED TABLE OF RFP CONTENTS

<b><u>PART I - THE SCHEDULE</u></b> .....	<b>1</b>
SECTION A - SOLICITATION/CONTRACT FORM .....	1
SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS .....	4
SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT .....	5
SECTION D - PACKAGING, MARKING AND SHIPPING .....	8
SECTION E - INSPECTION AND ACCEPTANCE .....	8
SECTION F - DELIVERIES OR PERFORMANCE .....	9
SECTION G - CONTRACT ADMINISTRATION DATA .....	10
SECTION H - SPECIAL CONTRACT REQUIREMENTS .....	17
<b><u>PART II - CONTRACT CLAUSES</u></b> .....	<b>24</b>
SECTION I - CONTRACT CLAUSES .....	24
<b><u>PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS</u></b> .....	<b>37</b>
SECTION J - LIST OF ATTACHMENTS .....	37
<b><u>PART IV - REPRESENTATIONS AND CERTIFICATIONS</u></b> .....	<b>38</b>
SECTION K - REPRESENTATIONS AND CERTIFICATIONS .....	38
SECTION L- INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS .....	39
SECTION M - EVALUATION FACTORS FOR AWARD .....	74

## PART I - THE SCHEDULE

THE CONTRACT SCHEDULE SET FORTH IN SECTIONS B THROUGH H, HEREIN, CONTAINS CONTRACTUAL INFORMATION PERTINENT TO THIS SOLICITATION. IT IS **NOT** AN EXACT REPRESENTATION OF THE PROPOSED CONTRACT DOCUMENT. CONTRACTUAL PROVISIONS PERTINENT TO THE OFFEROR (I.E., THOSE RELATING TO THE ORGANIZATIONAL STRUCTURE [E.G., NON-PROFIT, COMMERCIAL] AND SPECIFIC COST AUTHORIZATIONS UNIQUE TO THE OFFEROR'S PROPOSAL AND REQUIRING CONTRACTING OFFICER PRIOR APPROVAL) WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. HOWEVER, THE ENCLOSED CONTRACT SCHEDULE PROVIDES ALL THE NECESSARY INFORMATION FOR THE OFFEROR TO UNDERSTAND THE TERMS AND CONDITIONS OF THE RESULTANT CONTRACT.

## **SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS**

### **ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES**

The purpose of this contract is to conduct short-term and long-term studies of a variety of test articles by various routes of exposure. The project is designed to study diverse agents that may include: food additives, colorants or flavorings; pharmaceuticals and herbal remedies; herbicides, fungicides, and pesticides; ingredients found in soaps, lotions, perfumes, and cosmetics; in detergents and cleaners; in a wide variety of consumer products; used in manufacturing, or industrial settings, etc.

**The Government anticipates that studies of these test articles will be conducted approximately as follows: Three (3) test article study starts in fiscal year 2005 and four (4) test article study starts each year in fiscal years 2006 through 2010. Study Starts (including prestart efforts) will begin when a test article is identified and shipped to the contractor and may go on to include any but not necessarily all of the following: 14-day, 13-week and 2-year studies. The Government may, depending on need, the availability of funds, and the contractor's performance (reference ARTICLE G.8.) unilaterally exercise its option to conduct studies of one additional test article each year in years one through six of the contract. In addition to the deliverables set forth elsewhere in this Schedule, the contractor shall prepare and submit the study-specific and other reports set forth in ARTICLE C.2. and SECTION VI of Attachment 1, the Statement of Work, and any other reporting requirement(s) identified in the individual work assignment for the study of a test article.**

The design of actual studies will vary as needed depending on the individual test articles, route(s) of exposure, and endpoints to be evaluated. Study duration may be from a few days up to 2-years or lifetime; exposure may begin in utero or in young animals; the route of administration may be dosed feed, dosed water, gavage, dermal, parenteral (intraperitoneal, subcutaneous, intravenous, intratracheal).

All studies are to be conducted according to the requirements described in Attachment 2: Specifications for the Conduct of Studies to Evaluate the Toxic and Carcinogenic Potential of Chemical, Biological and Physical Agents in Laboratory Animals for the National Toxicology Program. Work is to be performed in accordance with the Good Laboratory Practice Regulations established by the FDA for Non-clinical Laboratory Studies (Fed. Register, Vol 52, # 172, Friday September 4, 1987, pp 33768-33782; 21 CFR Part 58). Details for typical 14-day, 13-week, 26/39-week and 2-year studies and specific requirements for individual routes of administration may be found in Attachment 2, the NTP Specifications.

Study designs will be provided for individual test articles along with a Schedule of Milestones and Deliverables. Four Sample Work Assignments are provided as part of Attachment 1, the Statement of Work, representing various routes of exposure, to determine contractor capabilities and to standardize costing by offerors. However, the type and number of studies to be conducted under this contract during each year may vary from the sample Work Assignments and projected schedule provided here.

### **NOTE TO OFFERORS: INSTRUCTIONS FOR PREPARATION OF TECHNICAL AND BUSINESS PROPOSALS**

**Four Sample Work Assignments (A, B, C, and D) have been included in Attachment 1, the Statement of work, to provide offerors some examples of study designs that might be conducted under this contract. Offerors are to provide technical and cost information in their proposal for each of the Sample Work Assignments.**

**Base Contract: The Government anticipates that studies of test articles will be conducted approximately as follows: Three (3) test article study starts in fiscal year 2005 and four (4) test article study starts each year in fiscal years 2006 through 2010. For estimating the total effort and costs for the 10-year period of this contract, offerors are to assume Work Assignments according to APPENDIX E: Schedule for Work Assignments, of Attachment 1, the Statement of Work, for the base contract.**

**Options:** The Government may, depending on need, the availability of funds, and the contractor's performance (reference ARTICLE G.8.) unilaterally exercise its option to conduct studies of one (1) additional test article each year in years one (1) through six (6) of the contract. For costing purposes, offerors are to assume the study type (13-week and 104-week gavage) and the schedule provided in APPENDIX F: Schedule for Optional Work Assignments, of Attachment 1, the Statement of Work for calculating costs and effort for these optional studies.

## **ARTICLE B.2. PRICES/COSTS**

The final contract will contain the price/cost provisions agreed upon by the Government and the Offeror.

## **ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS**

This article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer for: 1) Acquisition, by purchase or lease, of any interest in real property; 2) Special rearrangement or alteration of facilities; 3) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value; 4) Travel Costs; 5) Consultant Costs; 6) Subcontract Costs; 7) Patient Care Costs; 8) Accountable Government Property; and 9) Research Funding.

## **ARTICLE B.4. ADVANCE UNDERSTANDINGS**

Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost (e.g., foreign travel, consultant fees, subcontracts) will be included in this Article if the Contracting Officer has granted his/her approval prior to contract award.

## **SECTION C - WORK STATEMENT**

### **ARTICLE C.1. STATEMENT OF WORK**

Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work for the Conduct of Studies to Evaluate the Toxic and Carcinogenic Potential of Test Articles in Laboratory Animals for the National Toxicology Program (NTP), SECTION J, ATTACHMENT 1, and in accordance with the Specifications for the Conduct of Studies to Evaluate the Toxic and Carcinogenic Potential of Chemical, Biological and Physical Agents in Laboratory Animals for the National Toxicology Program (NTP) SECTION J, ATTACHMENT 2, attached hereto and made a part of this Solicitation.

The Contractor shall immediately report to the NIEHS any incident or unforeseeable occurrences not listed in the contract, Attachment 1, the Statement of Work, and Attachment 2, the Specifications, or any physical modifications to the laboratory facilities, as well as any changes in personnel that might have an impact on the conduct and results of the studies under the contract.

### **ARTICLE C.2. REPORTING REQUIREMENTS**

In addition to the required reports set forth elsewhere in this Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in the contract resulting from this solicitation. Narrative reports shall include charts, graphs, tabulations and pictures as necessary for explanation or support of the narrative. All final reports shall be dated and signed by the individual(s) responsible and the QAU. All reports shall be sent directly to the appropriate recipient as indicated in the table. The NIEHS will supply names of individual recipients as indicated.

**Each work assignment will specify the reporting requirements for the test article and will include a table listing the reporting requirements, the due dates, number of copies, and recipients.** General reporting requirements include but are not limited to the following:

A. PERIODIC REPORTS

1. Monthly Progress Report

A Monthly Progress Report shall be mailed by the fifteenth day of each month. Each Monthly Progress Report shall be submitted in the format specified in Attachment 2, Specifications. No QAU audit of this progress report is required.

2. Sanitization Methods Report

A Sanitization Methods Report shall be due 90 days after contract award and shall describe in detail:

- a. The methods being used (and/or proposed for future use) for sanitization of equipment used in the studies to include at least cages, racks, feeders, watering devices, magnetic field generating system, rooms, walls, halls and buildings. Describe methods in detail, including commercial products used, their EPA registration number and their chemical constituents if possible. Include any change made in procedure or products used in the appropriate Monthly Progress Report.
- b. The methods in use to keep animal quarters free of insects and other vermin. Again, specify commercial products used, EPA registration number and their chemical constituents, if possible. Report any changes in procedures or products used in the appropriate Monthly Progress Report.

3. Water Analysis

Water samples shall be collected for analysis and a report of the results submitted to the NTP at least once per year. An analysis is required during the in-life portion of the 13-week study and once each year during the two-year study. For laboratories that are not currently conducting studies for NTP, a report shall also be submitted within 30 days of contract award.

4. Health and Safety Chemical Hygiene Plan (General Facility Plan)

An NTP approved Health and Safety Plan is required prior to any work commencing under the contract. An updated Health and Safety plan shall be submitted to the NTP for review and approval every two years and anytime it is modified. Action to correct deficiencies shall be taken within 30 days of notification that such action is required.

5. Study Reports

Study Reports shall follow the Report Formats provided in the NTP Specifications and shall be submitted according to the Schedule of Milestones and Deliverables included in each Work Assignment.

6. Other Reports

Any incident or unforeseeable occurrences not listed in this document, or any physical modifications to the laboratory facilities, as well as any changes in personnel which might have an impact on the conduct and results of the studies shall be reported immediately to the NTP.

#### B. SUMMARY OF SALIENT RESULTS

The Contractor will be required to prepare and submit, with the final report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract. This report will be required on or before the expiration date of the contract.

#### C. INVENTION REPORTING REQUIREMENT

All reports and documentation required by [FAR Clause 52.227-11 / FAR Clause 52.227-11 (Deviation) / FAR Clause 52.227-13

*NOTE: The appropriate clause will be identified in any resultant contract]* including, but not limited to, the invention disclosure report, the confirmatory license, and the government support certification, shall be directed to the Office of Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 1040 A, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The annual utilization report shall be submitted one year from the contract effective date and annually thereafter. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted on the expiration date of the contract to the Contracting Officer to the following address:

Contracting Officer  
National Institute of Environmental Health Sciences, RCB  
National Institutes of Health  
79 T. W. Alexander Dr., 4401 Research Commons Building  
P.O. Box 12874  
Research Triangle Park, North Carolina 27709

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer at the address listed above.

To assist contractors in complying with invention reporting requirements of the clause, the NIH has developed "Interagency Edison," an electronic invention reporting system. Use of Interagency Edison is encouraged as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web (<http://www.iedison.gov>), or by contacting the Office of Extramural Inventions and Technology Resources Branch, OPERA, NIH.

## **SECTION D - PACKAGING, MARKING AND SHIPPING**

### **ARTICLE D.1. PACKAGING**

The Contractor shall package all data generated under this contract in accordance with Statement of Work for the Conduct of Studies to Evaluate the Toxic and Carcinogenic Potential of Test Articles in Laboratory Animals for the National Toxicology Program (NTP), SECTION J, ATTACHMENT 1, and in accordance with the Specifications for the Conduct of Studies to Evaluate the Toxic and Carcinogenic Potential of Chemical, Biological and Physical Agents in Laboratory Animals for the National Toxicology Program (NTP) SECTION J, ATTACHMENT 2.

### **ARTICLE D.2. MARKING**

The Contractor shall mark all data generated under this contract in accordance with Statement of Work for the Conduct of Studies to Evaluate the Toxic and Carcinogenic Potential of Test Articles in Laboratory Animals for the National Toxicology Program (NTP), SECTION J, ATTACHMENT 1, and in accordance with the Specifications for the Conduct of Studies to Evaluate the Toxic and Carcinogenic Potential of Chemical, Biological and Physical Agents in Laboratory Animals for the National Toxicology Program (NTP) SECTION J, ATTACHMENT 2.

### **ARTICLE D.3. SHIPPING**

The Contractor shall ship all data generated under this contract in accordance with Statement of Work for the Conduct of Studies to Evaluate the Toxic and Carcinogenic Potential of Test Articles in Laboratory Animals for the National Toxicology Program (NTP), SECTION J, ATTACHMENT 1, and in accordance with the Specifications for the Conduct of Studies to Evaluate the Toxic and Carcinogenic Potential of Chemical, Biological and Physical Agents in Laboratory Animals for the National Toxicology Program (NTP) SECTION J, ATTACHMENT 2.

## **SECTION E - INSPECTION AND ACCEPTANCE**

- a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.
- b. For the purpose of this SECTION, the Project Officer is the authorized representative of the Contracting Officer.
- c. Inspection and acceptance will be performed at destination (NIEHS, Research Triangle Park, NC). Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.
- d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR Clause No. 52.246-8, INSPECTION OF RESEARCH AND DEVELOPMENT -COST REIMBURSEMENT (MAY 2001)



## **SECTION F - DELIVERIES OR PERFORMANCE**

### **ARTICLE F.1 . DELIVERIES**

- a. Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in SECTION C., Article C.1., Attachments 1 and 2, and upon delivery in accordance with the stated delivery schedule and acceptance by the Contracting Officer, or the duly authorized representative, of the Nontechnical Items/Reports set forth in ARTICLES in SECTIONS C., G., and H. of the contract, and of the Technical Items/Reports described in SECTION C., ARTICLE C.2., Reporting Requirements, and the Schedule and Deliverables Section of Attachment 1, the Statement of Work (SOW).
- b. The technical and nontechnical items specified in SECTIONS C., G., and H., of the contract and the Schedule and Deliverables Section of ATTACHMENT 1, the SOW, will be required to be delivered F.O.B. Destination as set forth in FAR 52.247-35, F.O.B. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of the contract.

### **ARTICLE F.2. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)**

This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: <http://www.arnet.gov/far/>.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (AUGUST 1989) with ALTERNATE I (APRIL 1984).

## **SECTION G - CONTRACT ADMINISTRATION DATA**

Any contract awarded from this RFP will contain the following:

### **ARTICLE G.1. PROJECT OFFICER**

The following Project Officer(s) will represent the Government for the purpose of this contract:

[To be specified prior to award]

The Project Officer is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Government may unilaterally change its Project Officer designation.

### **ARTICLE G.2. KEY PERSONNEL**

- a. Pursuant to the Key Personnel clause in SECTION I, ARTICLE I.1., the following individual is considered to be essential to the work being performed hereunder:

NAME	TITLE
(To be specified prior to award)	Principal Investigator

- b. Prior to diverting any of the specified individuals to other programs, the Contractor shall notify the Contracting Officer reasonably in advance and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. No diversion shall be made by the Contractor without the written consent of the Contracting Officer; provided, that the Contracting Officer may ratify in writing such diversion and such ratification shall constitute the consent of the Contracting Officer required by this clause. The contract may be modified from time to time during the course of the contract to either add or delete personnel, as appropriate.
- c. When "key personnel" have been identified in this contract, it has been determined that such named personnel are necessary for the successful performance of this contract; and the Contractor agrees to assign such persons to the performance of the work under this contract, and shall not reassign or remove any of them without the consent of the Contracting Officer in accordance with the procedure outlined in e. below.
- d. In addition, during the first ninety (90) days of performance, the Contractor shall make no substitutions of key personnel unless the substitution is necessitated by illness, death, or termination of employment. The Contractor shall notify the Contracting Officer within 15 calendar days after the occurrence of any of these events and provide the information required by

paragraph e. below. After the initial ninety (90) day period, the Contractor shall submit the information required by paragraph e. to the Contracting Officer at least 15 days prior to making any permanent substitutions.

- e. The Contractor shall provide a detailed explanation of the circumstances necessitating the proposed substitutions, complete resumes for the proposed substitutes and any additional information requested by the Contracting Officer. Proposed substitutes shall have substantially equal abilities and qualifications to those of the persons being replaced. The Contracting Officer will notify the Contractor within 15 calendar days after receipt of all required information of the decision on substitutions. This article will be modified to reflect any approved changes of key personnel.
- f. Individuals assigned to fill the following discipline roles are considered to be "critical staff":

Toxicologist	Pathologist
Chemist	Laboratory Animal Veterinarian
Clinical Laboratory Scientist	Quality Assurance Unit Officer
Health and Safety Officer	GLP Study Director

The "critical staff" positions shall be filled by those individuals proposed in the Contractor's final proposal revision accepted by the Government. The Contractor agrees to make available such persons as have been proposed by the Contractor and approved by the Government for the above listed positions for the proposed work under this contract. The Contractor agrees to assign such persons to the performance of the work under this contract, and shall not reassign or remove any of them without the consent of the Project Officer. Whenever, for any reason one or more of the aforementioned personnel becomes unavailable for work under this contract, the Contractor shall immediately notify the Project Officer to that effect and shall, subject to the approval of the Project Officer in writing, replace such personnel with personnel of substantially equal ability and qualifications.

### ARTICLE G.3. WORK ASSIGNMENT PROCEDURES

Note: Individual Work Assignments may include options. The fee percentage on a work assignment shall not exceed the negotiated fee percentage on the contract. For planning purposes and to assist offerors in developing realistic estimates, Part I of the Work Assignment will identify an approximate period of performance for any option within the Work Assignment.

In providing support under this contract, the Contractor shall initiate work only when so directed by a Work Assignment (Attachment provided in Section J.). Approval of a Work Assignment shall not constitute approval to exceed any item listed in the contract or general clauses of the contract. **The fee percentage on a work assignment shall not exceed the negotiated fee percentage on the contract.** Work assignment amounts shall not exceed the total amounts listed in the contract (time, dollars, effort, consultants, travel, etc.). The Project Officer with Contracting Officer approval, is authorized to initiate Work Assignments and to sign Work Assignments indicating satisfactory performance/delivery of the services/product required in each Work Assignment. The Contractor shall assure, prior to commencing work on any Work Assignment, that written approval of the Project Officer and the Contracting Officer has been obtained. A Work Assignment which does not contain both Contracting Officer and Project Officer approval signatures shall be considered invalid and costs incurred for such work shall be considered unallowable. The Contractor shall not exceed the estimated labor hours, estimated Work Assignment amount, or change the Work Assignment leader without prior written approval of the Project Officer and the Contracting Officer by modification of the Work Assignment. The day-to-day operational and administrative details of the Work Assignment system will be established by the Project Officer with input from the Contractor. The Work Assignment system will operate within the following general guidelines:



a. Work Assignment (W.A.) Information

- (1) All work to be assigned under this contract shall relate directly to one or more of the task areas listed in the statement of work.
- (2) Each W.A. shall be written for the conduct of a specific, finite task.
- (3) Each new W.A. shall be numbered serially beginning with 01.
- (4) Each W.A. shall be completed on the form entitled "NIEHS Contract Work Assignment" and listed as an Attachment in Section J of this contract.
- (5) Upon award of the contract, an Administrative Work Assignment, as shown in SECTION J, Attachments, shall be issued. This Work Assignment will cover the time and expenditures necessary for the administration of the contract.

b. Initiation of a W.A.

- (1) The Project Officer will initiate Part I of the W.A.
- (2) The Contractor shall complete Part II and obtain the appropriate signature. The Contractor shall forward the proposed W.A. to the Project Officer.
- (3) Upon receipt of the proposed W.A. and after determining that the proposed W.A. is acceptable, the Project Officer will sign Part II to indicate recommendation for approval and forward to the Contracting Officer.
- (4) Upon receipt, the Contracting Officer will review the proposed W.A.
  - (a) If approved, the Contracting Officer will sign Part II to indicate approval and will forward the W.A. to the Contractor with a copy to the Project Officer.
  - (b) If not approved, the Contracting Officer will notify the Project Officer, stating the reasons for disapproval.
- (5) After receipt of the approved W.A., the Contractor shall begin work. The period of performance shall never precede the Contracting Officer Approval date.

c. Modification to a W.A.

- (1) Each amendment to an existing work assignment shall contain the original W.A. number and shall designate a modification number. Modification numbers for each W.A. shall be serially numbered beginning with 01 (for example, Work Assignment 01, Modification No. 01).
- (2) Each W.A. modification shall set forth in specific detail which portion(s) of the W.A. is to be modified. All Cost/Labor modifications shall be in the following format:

	Authorized to Date	This Modification	Revised Estimate
Labor Hours			
Cost Elements (List Each Element)			

d. Conclusion of a W.A.

- (1) For each W.A. performed, the Contractor shall prepare PART III of the W.A. for submission to the Contracting Officer.
- (2) This PART III submission shall include all actual information (cost, effort, and deliverables) relative to the W.A.
- (3) PART III of the W.A. shall be submitted as soon as possible and not to exceed three months after the closing date of the W.A. For those Work Assignments which expire within three months prior to the contract expiration date, PART III of the Work Assignment shall be submitted on the final contract day.
- (4) After verification that all work is complete and deliverables have been received and accepted, the Project Officer will sign Part III of the W.A. to indicate recommendation for approval and forward the W.A. to the Contracting Officer.
- (5) After verification that the W.A. has been satisfactorily completed, the Contracting Officer will approve completion of the W.A. by signing Part III of the W.A. and forward to the Contractor.

**ARTICLE G.4. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST**

- a. Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts NIH(RC)-1 are attached and made part of this contract. The instructions and the following directions for the submission of invoices/financing request must be followed to meet the requirements of a "proper" payment request pursuant to FAR 32.9.

- (1) Invoices/financing requests shall be submitted as follows:

An original and two copies to the following designated billing office:

Contracting Officer  
Research Contracts Branch  
National Institute of Environmental Health Sciences, NIH  
79 T.W. Alexander Drive, 4401 Research Commons Building  
P.O. Box 12874  
Research Triangle Park, North Carolina 27709

- (2) Inquiries regarding payment of invoices should be directed to the designated billing office, (919) 541-0416.

**OR**

#### ARTICLE G.4. LETTER OF CREDIT PAYMENT INFORMATION

- a. Advance payments will be provided under Letter of Credit Number \_\_\_\_\_ in accordance with Alternate V, Advance Payments Without Special Bank Account, of FAR Clause 52.232-12, Advance Payments. This clause is provided in full text in Article I.4. of this contract.

The contractor shall withdraw funds pursuant to Department of Treasury Circular 1075 (31 CFR Part 205, [http://www.access.gpo.gov/nara/cfr/waisidx\\_00/31cfr205\\_00.html](http://www.access.gpo.gov/nara/cfr/waisidx_00/31cfr205_00.html) ).

- (1) Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1, are attached and made a part of this contract for the submission of completion and/or final invoices. The invoice instructions and the following directions for the submission of invoices/financing requests must be followed to meet the requirements of a "proper" invoice, pursuant to FAR 32.9. The completion and/or final invoice shall be submitted as follows:

An original and two copies to the following office:

Contracting Officer  
Research Contracts Branch  
National Institute of Environmental Health Sciences, NIH  
79 T.W. Alexander Drive, 4401 Research Commons Building  
P.O. Box 12874  
Research Triangle Park, North Carolina 27709

- (2) Inquiries regarding payments should be directed to the following office administering advance payments:

Division of Payment Management  
11400 Rockville Pike  
Rockwall Building #1, Suite 700  
Rockville, MD 20852  
(<http://www.dpm.psc.gov/support/contact>)

#### ARTICLE G.5. CONTRACT FINANCIAL REPORT

- a. Financial reports on the attached Form NIH 2706, Financial Report of Individual Project/Contract, shall be submitted by the Contractor in accordance with the Instructions for Completing Form NIH 2706, which accompany the form, in an original and two copies, not later than the 30th working day after the close of the reporting period. The line entries for subdivisions of work and elements of cost (expenditure categories) which shall be reported within the total contract are listed in paragraph e., below. Subsequent changes and/or additions in the line entries shall be made in writing.
- b. Unless otherwise stated in that part of the Instructions for Completing Form NIH 2706, entitled "**PREPARATION INSTRUCTIONS**," all columns A through J, shall be completed for each report submitted.
- c. The first financial report shall cover the period consisting of the FIRST FULL THREE CALENDAR MONTHS following the date of the contract, in addition to any fractional part of the initial month. Thereafter, reports will be on a Quarterly basis.
- d. The Contracting Officer may require the Contractor to submit detailed support for costs contained in one or more interim financial reports. This clause does not supersede the record retention requirements in FAR Part 4.7.
- e. The following is a listing of expenditure categories to be reported:

<b>Expenditure Category</b>	<b>Percentage of</b>
<b>A</b>	<b>Effort/Hours</b>

- |      |                               |
|------|-------------------------------|
| (1)  | Direct Labor                  |
|      | (a) Principal Investigator    |
|      | (b) Co-Principal Investigator |
|      | (c) Key Personnel             |
|      | (i)                           |
|      | (ii)                          |
|      | (iii)                         |
| (2)  | Other Professional Personnel  |
| (3)  | Personnel - Other             |
| (4)  | Fringe Benefits               |
| (5)  | Accountable Personal Property |
| (6)  | Materials/Supplies            |
| (7)  | Travel                        |
| (8)  | Consultant Costs              |
| (9)  | Premium Pay                   |
| (10) | Computer Costs                |
| (11) | Subcontract Costs             |
| (12) | Other Direct Costs            |
| (13) | Indirect Costs                |
| (14) | G&A Expense                   |
| (15) | Total Cost                    |
| (16) | Fee                           |
| (17) | Total Cost Plus Fixed Fee     |

f. The Government may unilaterally revise the NIH 2706 to reflect the allotment of additional funds.

#### **ARTICLE G.6. INDIRECT COST RATES**

In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7(d)(2), "Allowable Cost and Payment" incorporated by reference in this contract in Part II, Section I, the cognizant Contracting Officer representative responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Director, Division of Financial Advisory Services  
Office of Contracts Management  
National Institutes of Health  
6100 Building, Room 6B05  
6100 EXECUTIVE BLVD MSC 7540  
BETHESDA MD 20892-7540

These rates are hereby incorporated without further action of the Contracting Officer.



## ARTICLE G.7. GOVERNMENT PROPERTY

- a. If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the DHHS Publication (OS) 686, entitled, **Contractor's Guide for Control of Government Property**, (1990) which can be found at <http://knownet.hhs.gov/log/contractorsguide.htm>
- b. Government Furnished Materials
  1. Test articles (unless specified otherwise)
  2. Methods for test article characterization – identity and purity (unless specified otherwise)
  3. Methods for dose formulation and dose analysis
  4. F344 rats and B6C3F1 mice
  5. TDMS equipment, software and user manuals
  6. Serology testing by an NTP contractor for animal disease screening

## ARTICLE G.8. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

### a. Contractor Performance Evaluations

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluation(s) will be prepared.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

### b. Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:  
[http://ocm.od.nih.gov/cdmp/cps\\_contractor.htm](http://ocm.od.nih.gov/cdmp/cps_contractor.htm)

The registration process requires the contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the contractor will be required to identify an alternate contact who will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

## **SECTION H - SPECIAL CONTRACT REQUIREMENTS**

### **ARTICLE H.1. REIMBURSEMENT OF COSTS FOR INDEPENDENT RESEARCH AND DEVELOPMENT PROJECTS (Commercials Only)**

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. This support is provided in the form of contracts and grants totaling approximately 7 billion dollars annually. PHS has established effective, time tested and well recognized procedures for stimulating and supporting this independent research by selecting from multitudes of applications those research projects most worthy of support within the constraints of its appropriations. The reimbursement through the indirect cost mechanism of independent research and development costs not incidental to product improvement would circumvent this competitive process.

To ensure that all research and development projects receive similar and equal consideration, all organizations may compete for direct funding of independent research and development projects they consider worthy of support by submitting those projects to the appropriate Public Health Service grant office for review. Since these projects may be submitted for direct funding, the Contractor agrees that no costs for any independent research and development project, including all applicable indirect costs, will be claimed under this contract.

### **ARTICLE H.2. HUMAN SUBJECTS**

It is hereby understood and agreed that research involving human subjects shall not be conducted under this contract, and that no material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used by the Contractor or made available by the Contractor for use by anyone other than the Government, for experimental or therapeutic use involving humans without the prior written approval of the Contracting Officer.

### **ARTICLE H.3. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH**

- a. Pursuant to Public Law(s) cited in paragraph b., below, NIH is prohibited from using appropriated funds to support human embryo research. Contract funds may not be used for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings.

<b>b. Public Law and Section No.</b>	<b>Fiscal Year</b>	<b>Period Covered</b>
P.L. 108-199, Title V - General Provisions, Section 510	2004	10/1/03 - 9/30/04

*Note: Any contract awarded as a result of this solicitation will include the appropriate fiscal year information.*

#### ARTICLE H.4. NEEDLE EXCHANGE

a. Pursuant to Public Law(s) cited in paragraph b., below, contract funds shall not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

b. Public Law and Section No.	Fiscal Year	Period Covered
P.L. 108-199, Title V - General Provisions, Section 505	2004	10/1/03 - 9/30/04

*Note: Any contract awarded as a result of this solicitation will include the appropriate fiscal year information.*

#### ARTICLE H.5. ANIMAL WELFARE

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. This policy may be accessed at <http://grants1.nih.gov/grants/olaw/references/phspol.htm><http://grants1.nih.gov/grants/olaw/references/phspol.htm>

#### ARTICLE H.6. INTRODUCTION OF RODENTS AND RODENT PRODUCTS

No rodent or rodent product shall be delivered to NIEHS directly, or through collaborative research or holding facilities under contract to NIEHS except by prior approval by the Comparative Medicine Branch, NIEHS. The approval form, Application to Introduce Rodents and Rodent Products into NIEHS, is available by contacting the Comparative Medicine Branch, Quality Assurance Laboratory at 919-541-3239. Approval must be obtained by the Contractor prior to shipment to NIEHS of the rodents and/or rodent products. The Contractor must be sure that this approval exists and is current before transferring rodents or rodent products into the NIEHS. Refusal or negligence to do so will be considered a material breach of contract and may be treated as any other such material breach. Requests for approval should be submitted within 30 days of the shipping date to: NIEHS, Comparative Medicine Branch, Quality Assurance laboratory, PO box 12233, MD C1-06, Building 101, Room C128, Research Triangle park, NC, 27709. United States Department of Agriculture permits are required for the importation of monoclonal antibodies, hybridoma cell lines, cell cultures, and other biologic materials that have been in contact with material of animal origin. USDA permit forms and information are available on-line at <http://www.aphis.usda.gov/forms/index.html#VS16>. A copy of the completed form should be submitted to the Comparative Medicine Branch.

#### ARTICLE H.8. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

- (1) The Small Business Subcontracting Plan, dated *(to be inserted prior to contract award)* is attached hereto and made a part of this contract.
- (2) The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

b. Subcontracting Reports

- (1) **Subcontracting Report for Individual Contracts, SF-294**

The Contractor shall submit the original and one (1) copy of Subcontracting Report for Individual Contracts, SF-294 in accordance with the instructions on the report as referenced in Public Law 95-507, Section 211. In addition to the information contained in the General Instructions on the back of this form for Block 17, "Remarks," the Contractor shall provide an explanation **for any category** of small business subcontracting for which there were no dollars reported since the last reporting period.

Regardless of the effective date of this contract, the Report shall be submitted on the following dates for the entire life of this contract:

April 30th  
October 30th

The Report shall be sent to the Contracting Officer at following address:

Contracting Officer  
Research Contracts Branch  
National Institute of Environmental Health Sciences, NIH  
79 T.W. Alexander Drive, 4401 Research Commons Building  
P.O. Box 12874  
Research Triangle Park, North Carolina 27709

(2) **Summary Subcontract Report, SF-295**

The Contractor shall submit two (2) copies of Summary Subcontract Report, SF-295 in accordance with the instructions on the report as referenced in Public Law 95-507, Section 211. Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

October 30th

One copy of this report shall be sent to the Contracting Officer at the address above. One copy of this Report shall be mailed to the Office of Small and Disadvantaged Business Utilization, DHHS at the following addresses:

**Office of Small and Disadvantaged Business Utilization**  
Department of Health and Human Services  
Hubert H. Humphrey Bldg., Room 517-D  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

- (3) The contractor shall also send an "Information Copy" of the SF-295 to the Cognizant Commercial Representative (CMR) at the address provided by the SBA. The Contractor should call SBA Headquarters in Washington, DC at (202) 606-4000, X234 for the correct address if unknown.

**ARTICLE H.9. SALARY RATE LIMITATION LEGISLATION PROVISIONS**

*Note: Any contract awarded as a result of this solicitation will include the appropriate fiscal year information.*

- a. Pursuant to Public Law(s) cited in paragraph b., below, no NIH Fiscal Year funds may be used to pay the direct salary of an individual through this contract at a rate in excess of applicable amount shown for the fiscal year covered. Direct salary is exclusive of fringe benefits, overhead, and general and administrative expenses (also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an

individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor. The per year salary rate limit also applies to individuals proposed under subcontracts. It does not apply to fees paid to consultants. If this is a multiple year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate exceeds any salary rate ceiling established in future HHS appropriation acts.

	Fiscal Year	Dollar Amount of Salary Limitation*
b. <b>Public Law No.</b>		<b>Executive Level I</b>
P.L. 108-199, Title II, General Provisions, Section 204	2004	
c. Direct salaries which will be paid with FY-04 funds are limited to the Executive level I rate which was in effect on the date(s) the expense was incurred.		

*\*For contract expenditures using FY-04 funds, the Executive Level I rate for the period 10/1/03 – 12/31/03 is \$171,900. Effective 1/1/04, for contract expenditures using FY-04 funds, the Executive Level I rate was increased to \$174,500 and will remain at this level until such time as it is determined to raise the Executive Schedule annual rates. See the web site listed below for Executive Schedule rates of pay.*

**LINK to EXECUTIVE SCHEDULE SALARIES:** <http://www.opm.gov/oca/PAYRATES/index.htm>  
(Click on "Executive Schedule" for the current Fiscal Year's salary rate or scroll down to the "General Schedule Salary Tables from Previous Years" to locate the Executive Level salary rates from previous years.)

#### ARTICLE H.10. INFORMATION TECHNOLOGY SYSTEMS SECURITY SPECIFICATIONS

The contractor agrees to comply with the Information Technology (IT) systems security and/or privacy specifications set forth herein; the Computer Security Act of 1987; Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems," and the DHHS Automated Information Systems Security Program (AISSP) Handbook, which may be found at the following websites:

Computer Security Act of 1987: [http://csrc.ncsl.nist.gov/secplcy/csa\\_87.txt](http://csrc.ncsl.nist.gov/secplcy/csa_87.txt)  
OMB A-130, Appendix III: <http://csrc.ncsl.nist.gov/secplcy/a130app3.txt>  
DHHS AISSP Handbook: <http://irm.cit.nih.gov/policy/aissp.html>

The contractor further agrees to include this provision in any subcontract awarded pursuant to this prime contract. Failure to comply with these requirements shall constitute cause for termination.

The contractor shall be responsible for properly protecting all information used, gathered, or developed as a result of the SOW. The contractor shall establish and implement appropriate administrative, technical, and physical safeguards to ensure the security and confidentiality of sensitive Government information, data, and/or equipment.

In addition, during all activities and operations on Government premises, the contractor shall comply with DHHS, including National Institutes of Health (NIH), rules of conduct.

##### a. Required IT Systems Security Training

The contractor shall assure that each employee has completed the NIH Computer Security Awareness Training (<http://irtsectraining.nih.gov/>) prior to performing any work under this contract.

The contractor shall maintain a listing by name and title of each individual working under this contract who has completed the NIH required training. Any additional security training completed by contractor staff shall be included on this listing. The listing of completed training shall be included in the first technical progress report. (See Article C.2. Reporting Requirements) Any revisions to this listing as a result of staffing changes shall be submitted with next required technical progress report.

b. Position Sensitivity Designations

The Government has determined that the following position sensitivity designations and associated clearance and investigation requirements apply under this contract:

**Level 1C: Non Sensitive (Requires Suitability Determination with an NACI).**

Contractor employees assigned to a Level 1C position are subject to a National Agency Check and Inquiry Investigation (NACI).

Applicable contractor positions: All contract employees who will be involved in data entry, report generation, and system maintenance (to include validation and upgrade) for IT systems in support of work required by Attachment 1, the statement of Work, and Attachment 2, the Specifications, of any contract.

Contractor employees who have met investigative requirements within the past five years may only require an updated or upgraded investigation. Verifications of completed investigations (e.g. copies of certificates of investigations or security clearances), as well as requests for new investigations, shall be submitted to the Project Officer.

c. Commitment to Protect Sensitive Information

1. Contractor Agreement

The Contractor shall not release, publish, or disclose sensitive information to unauthorized personnel, and shall protect such information in accordance with provisions of the following laws and any other pertinent laws and regulations governing the confidentiality of sensitive information:

- 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records)
- 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information)
- Public Law 96-511 (Paperwork Reduction Act)

2. Contractor-Employee Non-Disclosure Agreements

Each contractor employee who may have access to sensitive information under this contract shall complete the attachment entitled, "Commitment To Protect Non-Public Information - Contractor Agreement," which is referenced in Section J of this contract and available at: <http://irm.cit.nih.gov/security/Nondisclosure.pdf>

A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the Project Officer prior to performing any work under the contract.

**ARTICLE H.11 . CONFIDENTIALITY OF INFORMATION**

The following information is covered by HHSAR 352.224-70, Confidentiality of Information (APRIL 1984): preliminary data submissions and final study reports.

**ARTICLE H.12 . PUBLICATION AND PUBLICITY**

The contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Institute of Environmental Health Sciences, National Institutes of Health, Department of Health and Human Services, under Contract No. .

#### **ARTICLE H.13 . PRESS RELEASES**

a. Pursuant to Public Law(s) cited in paragraph b., below, the contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

<b>b. Public Law and Section No.</b>	<b>Fiscal Year</b>	<b>Period Covered</b>
P.L. 108-199, Title V – General Provisions, Section 507	<b>2004</b>	<b>10/1/03 – 9/30/04</b>

*Note: Any contract awarded as a result of this solicitation will include the appropriate fiscal year information.*

#### **ARTICLE H.14. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE**

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477)**. All telephone calls will be handled confidentially. The e-mail address is **Htips@os.dhhs.gov** and the mailing address is:

Office of Inspector General  
Department of Health and Human Services  
TIPS HOTLINE  
P.O. Box 23489  
Washington, D.C. 20026

#### **ARTICLE H.15. YEAR 2000 COMPLIANCE**

In accordance with FAR 39.106, Information Technology acquired under this contract must be Year 2000 compliant as set forth in the following clause:

##### **1. Service Involving the Use of Information Technology**

##### **YEAR 2000 COMPLIANCE--SERVICE INVOLVING THE USE OF INFORMATION TECHNOLOGY**

The Contractor agrees that each item of hardware, software, and firmware used under this contract shall be able to accurately process date data (including, but not limited to, calculating, comparing and sequencing) from, into and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations.

## ARTICLE H.16. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

Unique research resources arising from NIH-funded research are to be shared with the scientific research community. NIH provides guidance, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090]), concerning the appropriate terms for disseminating and acquiring these research resources. This guidance, found at : <http://ott.od.nih.gov/NewPages/64FR72090.pdf>, is intended to help contractors ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

*Note: For the purposes of this Article, the terms, "research tools," "research materials," and "research resources" are used interchangeably and have the same meaning.*

## ARTICLE H.17. ANTI -LOBBYING

- a. Pursuant to Public Law(s) cited in paragraph c., below, contract funds shall not be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself.
- b. Contract funds shall not be used to pay salary or expenses of the contractor or any agent acting for the contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

c.	Public Law and Section No.	Fiscal Year	Period Covered
	for a., above: P.L. 108-199 Title V - General Provisions, Section 503a	2004	10/1/03-9/30/04
	for b, above: P.L. 108-199 Title V - General Provisions, Section 503b	2004	10/1/03-9/30/04

*Note: Any contract awarded as a result of this solicitation will include the appropriate fiscal year information.*

## ARTICLE H.18. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in ARTICLE I.3., the contract will consist only of the base contract as defined in Sections B and C of the contract and Attachment 1, the Statement of Work. Pursuant to clause 52.217-7 set forth in ARTICLE I.3. of this contract and evaluation(s) of the contractor's performance (reference ARTICLE G.8.), the Government may, by unilateral contract modification, require the Contractor to perform additional studies (one optional work assignment in FY2005 through FY2010) as set forth in Sections B and C of the contract and Appendix F, Schedule for Optional Work Assignments, of Attachment 1, the Statement of Work. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the estimated cost plus fixed fee of the contract will be increased as set forth in Article B.3.



## **PART II - CONTRACT CLAUSES**

### **SECTION I - CONTRACT CLAUSES**

THE FOLLOWING PAGES CONTAIN A LISTING(S) OF GENERAL CLAUSES WHICH WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSES LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP.

#### **ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT - FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)**

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: <http://www.arnet.gov/far/>.

##### **a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:**

<u>FAR CLAUSE NO.</u>	<u>DATE</u>	<u>TITLE</u>
52.202-1	Jul 2004	Definitions
52.203-3	Apr 1984	Gratuities (Over \$100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over \$100,000)
52.203-6	Jul 1995	Restrictions on Subcontractor Sales to the Government (Over \$100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures (Over \$100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over \$100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over \$100,000)
52.203-12	Jun 2003	Limitation on Payments to Influence Certain Federal Transactions (Over \$100,000)
52.204-4	Aug 2000	Printed or Copied Double-Sided on Recycled Paper (Over \$100,000)
52.204-7	Oct 2003	Central Contractor Registration
52.209-6	Jul 1995	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over \$25,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over \$100,000)
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over \$500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over \$100,000)

52.215-15	Jan 2004	Pension Adjustments and Asset Reversions
52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.216-7	Dec 2002	Allowable Cost and Payment
52.216-8	Mar 1997	Fixed Fee
52.219-8	May 2004	Utilization of Small Business Concerns (Over \$100,000)
52.219-9	Jan 2002	Small Business Subcontracting Plan (Over \$500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over \$500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over \$100,000) (Note: The dollar amount in paragraph (a) of this clause is \$0 unless otherwise specified in the contract.)
52.222-3	Jun 2003	Convict Labor
52.222-26	Apr 2002	Equal Opportunity
52.222-35	Dec 2001	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Dec 2001	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.223-6	May 2001	Drug-Free Workplace
52.223-14	Aug 2003	Toxic Chemical Release Reporting (Over \$100,000)
52.225-1	Jun 2003	Buy American Act - Supplies
52.225-13	Dec 2003	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over \$100,000)
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (Note: In accordance with FAR 27.303(a)(2), paragraph (f) is modified to include the requirements in FAR 27.303(a)(2)(i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Jun 1987	Rights in Data - General
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	Jun 1996	Interest (Over \$100,000)
52.232-20	Apr 1984	Limitation of Cost

52.232-23	Jan 1986	Assignment of Claims
52.232-25	Oct 2003	Prompt Payment, Alternate I (Feb 2002)
52.232-33	Oct 2003	Payment by Electronic Funds Transfer--Central Contractor Registration
52.233-1	Jul 2002	Disputes
52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2001	Penalties for Unallowable Costs (Over \$500,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over \$100,000)
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B, Advance Understandings.
52.244-5	Dec 1996	Competition in Subcontracting (Over \$100,000)
52.245-5	May 2004	Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract)
52.246-23	Feb 1997	Limitation of Liability (Over \$100,000)
52.249-6	Sep 1996	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays
52.253-1	Jan 1991	Computer Generated Forms

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES:

<u>HHSAR CLAUSE NO.</u>	<u>DATE</u>	<u>TITLE</u>
352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
352.216-72	Oct 1990	Additional Cost Principles
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.232-9	Apr 1984	Withholding of Contract Payments
352.233-70	Apr 1984	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings
352.270-5	Apr 1984	Key Personnel
352.270-6	Jul 1991	Publications and Publicity

[ End of GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT - Rev. 07/2004].

OR

**ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT CONTRACT WITH EDUCATIONAL INSTITUTIONS - FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)**

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: <http://www.arnet.gov/far/>.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

<u>FAR CLAUSE NO.</u>	<u>DATE</u>	<u>TITLE</u>
52.202-1	Jul 2004	Definitions
52.203-3	Apr 1984	Gratuities (Over \$100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over \$100,000)
52.203-6	Jul 1995	Restrictions on Subcontractor Sales to the Government (Over \$100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures (Over \$100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over \$100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over \$100,000)
52.203-12	Jun 2003	Limitation on Payments to Influence Certain Federal Transactions (Over \$100,000)
52.204-4	Aug 2000	Printed or Copied Double-Sided on Recycled Paper (Over \$100,000)
52.204-7	Oct 2003	Central Contractor Registration
52.209-6	Jul 1995	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over \$25,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over \$100,000), Alternate II (Apr 1998)
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over \$500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over \$100,000)
52.215-15	Jan 2004	Pension Adjustments and Asset Reversions

52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.216-7	Dec 2002	Allowable Cost and Payment (Paragraph (a) is modified to delete the words "Subpart 31.2" and to add the words "Subpart 31.3")
52.216-11	Apr 1984	Cost Contract - No Fee
52.219-8	May 2004	Utilization of Small Business Concerns (Over \$100,000)
52.219-9	Jan 2002	Small Business Subcontracting Plan (Over \$500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over \$500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over \$100,000) (Note: The dollar amount in paragraph (a) of this clause is \$0 unless otherwise specified in the contract.)
52.222-3	Jun 2003	Convict Labor
52.222-26	Apr 2002	Equal Opportunity
52.222-35	Dec 2001	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Dec 2001	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.223-6	May 2001	Drug-Free Workplace
52.223-14	Aug 2003	Toxic Chemical Release Reporting (Over \$100,000)
52.225-1	Jun 2003	Buy American Act - Supplies
52.225-13	Dec 2003	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over \$100,000)
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (Note: In accordance with FAR 27.303(a)(2), paragraph (f) is modified to include the requirements in FAR 27.303(a)(2)(i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Jun 1987	Rights in Data - General
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims

52.232-25	Oct 2003	Prompt Payment, Alternate I (Feb 2002)
52.232-33	Oct 2003	Payment by Electronic Funds Transfer--Central Contractor Registration
52.233-1	Jul 2002	Disputes
52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over \$100,000)
52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B, Advance Understandings.
52.244-5	Dec 1996	Competition in Subcontracting (Over \$100,000)
52.245-5	May 2004	Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract), Alternate I (Jul 1985)
52.246-23	Feb 1997	Limitation of Liability (Over \$100,000)
52.249-5	Sep 1996	Termination for the Convenience of the Government (Educational and Other Nonprofit Institutions)
52.253-1	Jan 1991	Computer Generated Forms

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES

HHSAR CLAUSE		
<u>NO.</u>	<u>DATE</u>	<u>TITLE</u>
352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
352.216-72	Oct 1990	Additional Cost Principles
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.232-9	Apr 1984	Withholding of Contract Payments
352.233-70	Apr 1984	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings
352.249-14	Apr 1984	Excusable Delays
352.270-5	Apr 1984	Key Personnel
352.270-6	Jul 1991	Publications and Publicity
352.270-7	Jan 2001	Paperwork Reduction Act

[ End of GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT CONTRACT WITH EDUCATIONAL INSTITUTIONS - Rev. 07/2004].

OR

**ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT CONTRACT WITH NONPROFIT ORGANIZATIONS OTHER THAN EDUCATIONAL INSTITUTIONS - FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)**

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: <http://www.arnet.gov/far/>.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

<u>FAR CLAUSE NO.</u>	<u>DATE</u>	<u>TITLE</u>
52.202-1	Jul 2004	Definitions
52.203-3	Apr 1984	Gratuities (Over \$100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over \$100,000)
52.203-6	Jul 1995	Restrictions on Subcontractor Sales to the Government (Over \$100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures (Over \$100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over \$100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over \$100,000)
52.203-12	Jun 2003	Limitation on Payments to Influence Certain Federal Transactions (Over \$100,000)
52.204-4	Aug 2000	Printed or Copied Double-Sided on Recycled Paper (Over \$100,000)
52.204-7	Oct 2003	Central Contractor Registration
52.209-6	Jul 1995	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over \$25,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over \$100,000), Alternate II (Apr 1998)
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over \$500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over \$100,000)
52.215-15	Jan 2004	Pension Adjustments and Asset Reversions
52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes

52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.216-7	Dec 2002	Allowable Cost and Payment (Paragraph (a) is modified to delete the words "Subpart 31.2" and to add the words "Subpart 31.7")
52.216-11	Apr 1984	Cost Contract - No Fee
52.219-8	May 2004	Utilization of Small Business Concerns (Over \$100,000)
52.219-9	Jan 2002	Small Business Subcontracting Plan (Over \$500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over \$500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over \$100,000) (Note: The dollar amount in paragraph (a) of this clause is \$0 unless otherwise specified in the contract.)
52.222-3	Jun 2003	Convict Labor
52.222-26	Apr 2002	Equal Opportunity
52.222-35	Dec 2001	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Dec 2001	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.223-6	May 2001	Drug-Free Workplace
52.223-14	Aug 2003	Toxic Chemical Release Reporting (Over \$100,000)
52.225-1	Jun 2003	Buy American Act - Supplies
52.225-13	Dec 2003	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over \$100,000)
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (Note: In accordance with FAR 27.303(a)(2), paragraph (f) is modified to include the requirements in FAR 27.303(a)(2)(i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Jun 1987	Rights in Data - General
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Oct 2003	Prompt Payment, Alternate I (Feb 2002)
52.232-33	Oct 2003	Payment by Electronic Funds Transfer--Central Contractor Registration
52.233-1	Jul 2002	Disputes



52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2001	Penalties for Unallowable Costs (Over \$500,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over \$100,000)
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B, Advance Understandings.
52.244-5	Dec 1996	Competition in Subcontracting (Over \$100,000)
52.245-5	May 2004	Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract), Alternate I (Jul 1985)
52.246-23	Feb 1997	Limitation of Liability (Over \$100,000)
52.249-5	Sep 1996	Termination for the Convenience of the Government (Educational and Other Nonprofit Institutions)
52.253-1	Jan 1991	Computer Generated Forms

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR)  
(48 CFR CHAPTER 3) CLAUSES

HHSAR <u>CLAUSE</u>		
<u>NO.</u>	<u>DATE</u>	<u>TITLE</u>
352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
352.216-72	Oct 1990	Additional Cost Principles
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.232-9	Apr 1984	Withholding of Contract Payments
352.233-70	Apr 1984	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings
352.249-14	Apr 1984	Excusable Delays
352.270-5	Apr 1984	Key Personnel
352.270-6	Jul 1991	Publications and Publicity
352.270-7	Jan 2001	Paperwork Reduction Act

[ End of GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT CONTRACT WITH  
NONPROFIT ORGANIZATIONS OTHER THAN EDUCATION INSTITUTIONS - Rev. 07/2004].

## ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/ Contractor will be determined during negotiations.

It is expected that the following clause(s) will be made part of the resultant contract:

ALTERNATE II (OCTOBER 2001) of FAR Clause 52.219-9, SMALL BUSINESS SUBCONTRACTING PLAN (JANUARY 2002) is added.

FAR Clause 52.232-20, LIMITATION OF COST, is deleted in its entirety and FAR Clause 52.232-22, LIMITATION OF FUNDS (APRIL 1984) is substituted therefor. **Note: When this contract is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.**

## ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

Additional clauses other than those listed below which are based on the type of contract/ Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following: This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

### a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

- (1) FAR 52.217-7, Option for Increased Quantity - Separately Priced Line Item (MARCH 1989).  
"....The Contracting Officer may exercise the option by written notice to the Contractor within the time frames set forth in Attachment 1, the Statement of Work"
- (2) FAR 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (JANUARY 1999).  
    "(c) Waiver of evaluation preference.....  
        [ ] Offeror elects to waive the evaluation preference."
- (3) FAR 52.227-14, Rights in Data - General (JUNE 1987).
- (4) Alternate II (JUNE 1987), FAR 52.227-14, Rights in Data--General (JUNE 1987).  
Paragraph (g)(2) is modified to add items listed in FAR 27.404(d)(1)(i), (ii), and (iii).
- (5) Alternate V (JUNE 1987), FAR 52.227-14, Rights in Data--General (JUNE 1987).  
Specific data items that are not subject to paragraph (j) include: None.
- (6) FAR 52.230-2, Cost Accounting Standards (APRIL 1998).
- (7) FAR 52.230-3, Disclosure and Consistency of Cost Accounting Practices (APRIL 1998).
- (8) FAR 52.230-6, Administration of Cost Accounting Standards (NOVEMBER 1999).
- (9) FAR 52.242-3, Penalties for Unallowable Costs (MAY 2001).
- (10) FAR 52.251-1, Government Supply Sources (APRIL 1984).

- b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:
- (1) HHSAR 352.223-70, Safety and Health (JANUARY 2001). [This clause is provided in full text in SECTION J - ATTACHMENTS.]
  - (2) HHSAR 352.224-70, Confidentiality of Information (APRIL 1984).

(3) HHSARS 352.270-9, Care of Live Vertebrate Animals (JANUARY 2001).

c. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:

The following clauses are attached and made a part of this contract:

(1) NIH (RC)-7, Procurement of Certain Equipment (APRIL 1984) (OMB Bulletin 81-16).

**ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT**

Additional clauses other than those listed below which are based on the type of contract/ Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following: This contract incorporates the following clauses in full text.

FEDERAL ACQUISITION REGULATION (FAR)(48 CFR CHAPTER 1) CLAUSES:

**IF ANY CONTRACT IS AWARDED USING THE LETTER OF CREDIT PAYMENT MECHANISM, THE FOLLOWING CLAUSE WOULD APPLY:**

a. **ALTERNATE V, ADVANCE PAYMENT WITHOUT SPECIAL ACCOUNT (MAY 2001), ALTERNATE II (MAY 2001), and ALTERNATE IV (APRIL 1984), of FAR Clause 52.232-12, ADVANCE PAYMENTS (MAY 2001).**

- (a) Requirements for payment. Advance payments will be made under this contract (1) upon submission of properly certified invoices or vouchers by the contractor, and approval by the administering office, National Institute of Environmental Health Sciences, or (2) under a letter of credit. The amount of the invoice or voucher submitted plus all advance payments previously approved shall not exceed \$ \_\_\_\_\_. If a letter of credit is used, the Contractor shall withdraw cash only when needed for disbursements acceptable under this contract and report cash disbursements and balances as required by the administering office. The Contractor shall apply terms similar to this clause to any advance payments to subcontractors.
- (b) *Use of funds.* The Contractor may use advance payment funds only to pay for properly allocable, allowable, and reasonable costs for direct materials, direct labor, and indirect costs. Determinations of whether costs are properly allocable, allowable, and reasonable shall be in accordance with generally accepted accounting principles, subject to any applicable subparts of Part 31 of the Federal Acquisition Regulation.
- (c) *Repayment to the Government.* At any time, the Contractor may repay all or any part of the funds advanced by the Government. Whenever requested in writing to do so by the administering office, the Contractor shall repay to the Government any part of unliquidated advance payments considered by the administering office to exceed the Contractor's current requirements or the amount specified in paragraph (a) of this clause.
- (d) *Maximum payment.* When the sum of all unliquidated advance payments, unpaid interest charges, and other payments equal the total estimated cost of \$ \_\_\_\_\_ (not including fixed-fee, if any) for the work under this contract, the Government shall withhold further payments to the Contractor. Upon completion or termination of the contract, the Government shall deduct from the amount due to the Contractor all unliquidated advance payments and interest charges payable. The Contractor shall pay any deficiency to the Government upon demand. For purposes of this paragraph, the estimated cost shall be considered to be the stated estimated cost, less any subsequent reductions of the estimated

cost, plus any increases in the estimated costs that do not, in the aggregate, exceed \$ \_\_\_\_\_.  
[Insert an amount not higher than 10 percent of the stated estimated cost inserted in this paragraph].  
The estimated cost shall include, without limitation, any reimbursable cost (as estimated by the Contracting Officer) incident to a termination for the convenience of the Government. Any payments withheld under this paragraph shall be applied to reduce the unliquidated advance payments. If full liquidation has been made, payments under the contract shall resume.

- (e) *Interest.* No interest shall be charged to the prime Contractor for advance payments except for interest charged during a period of default. The terms of this paragraph concerning interest charges for advance payments shall not apply to the prime Contractor.
- (1) The Contractor shall pay interest to the Government on the daily unliquidated advance payments at the daily rate specified in subparagraph (e)(3) below. Interest shall be computed at the end of each calendar month for the actual number of days involved. For the purpose of computing the interest charge, the following shall be observed:
- (i) Advance payments shall be considered as increasing the unliquidated balance as of the date of the advance payment check.
  - (ii) Repayments by Contractor check shall be considered as decreasing the unliquidated balance as of the date on which the check is received by the Government authority designated by the Contracting Officer.
  - (iii) Liquidations by deductions from payments to the Contractor shall be considered as decreasing the unliquidated balance as of the dates on which the Contractor presents to the Contracting Officer full and accurate data for the preparation of each voucher. Credits resulting from these deductions shall be made upon the approval of the reimbursement vouchers by the Disbursing Officer, based upon the Contracting Officer's certification of the applicable dates.
- (2) Interest charges resulting from the monthly computation shall be deducted from any payments on account of the fixed-fee due to the Contractor. If the accrued interest exceeds the payment due, any excess interest shall be carried forward and deducted from subsequent payments of the contract price or fixed-fee. Interest carried forward shall not be compounded. Interest on advance payments shall cease to accrue upon (i) satisfactory completion or (ii) termination of the contract for the convenience of the Government. The Contractor shall charge interest on advance payments to subcontractors in the manner described above and credit the interest to the Government. Interest need not be charged on advance payments to nonprofit educational or research subcontractors for experimental, developmental, or research work.
- (3) If interest is required under the contract, the Contracting Officer shall determine a daily interest rate based on the rate established by the Secretary of the Treasury under Pub. L. 92-41 (50 U.S.C. App., 1215(b)(2)). The Contracting Officer shall revise the daily interest rate during the contract period in keeping with any changes in the cited interest rate.

- (4) If the full amount of interest charged under this paragraph has not been paid by deduction or otherwise upon completion or termination of this contract, the Contractor shall pay the remaining interest to the Government on demand.

b. **FAR Clause 52.244-6, SUBCONTRACTS FOR COMMERCIAL ITEMS (APRIL 2003)**

- (a) **Definitions.** As used in this clause--

**Commercial item**, has the meaning contained in the clause at 52.202-1, Definitions.

**Subcontract**, includes a transfer of commercial items between divisions, subsidiaries, or affiliates of the Contractor or subcontractor at any tier.

- (b) To the maximum extent practicable, the Contractor shall incorporate, and require its subcontractors at all tiers to incorporate, commercial items or nondevelopmental items as components of items to be supplied under this contract.

- (c) (1) The Contractor shall insert the following clauses in subcontracts for commercial items:

- (i) 52.219-8, Utilization of Small Business Concerns (OCT 2000) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds \$500,000 (\$1,000,000 for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.
- (ii) 52.222-26, Equal Opportunity (APR 2002) (E.O. 11246).
  - (iii) 52.222-35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (DEC 2001) (38 U.S.C. 4212(a)).
- (iv) 52.222-36, Affirmative Action for Workers with Disabilities (JUN 1998) (29 U.S.C. 793).
- (v) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (APR 2003) (46 U.S.C. Appx 1241 and 10 U.S.C. 2631) (flow down required in accordance with paragraph (d) of FAR clause 52.247-64).

- (2) While not required, the Contractor may flow down to subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

- (d) The Contractor shall include the terms of this clause, including this paragraph (d), in subcontracts awarded under this contract.

## PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

### SECTION J - LIST OF ATTACHMENTS

#### Documents to be Attached to Any Contract Resulting from the RFP

1. Statement of Work for Studies to Evaluate the Toxic and Carcinogenic Potential of Test Articles in Laboratory Animals for the National Toxicology Program (NTP) dated August 2004
2. Specifications for the Conduct of Studies to Evaluate the Toxic and Carcinogenic Potential of Chemical, Biological, and Physical Agents in Laboratory Animals for the National Toxicology Program
3. Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1 May, 1997, 4 pages.
4. Financial Report of Individual Project/Contract, NIH 2706 , May, 1997, 1 page.
5. Instructions for Completing Form NIH 2706, May, 1997, 3 pages.
6. Safety and Health , HHSAR Clause 352.223-70, January, 2001, 1 page.
7. Procurement of Certain Equipment, NIH(RC)-7 (OMB Bulletin 81-16) , April, 1984, 1 page.

#### Forms for Informational Purposes Only

8. Background Information for Work Assignments
9. Sample Work Assignment, April, 1995, 3 pages
10. Packaging and Delivery of Proposal, 1 page.

#### Technical Proposal Forms – (Offeror(s) are to complete and submit with their Technical Proposal.)

11. Summary of Related Activities, March, 1984, 1 page.
12. Technical Proposal Cost Information , December, 1988, 1 page.
13. Government Notice for Handling Proposals, January, 2001, 1 page.
14. Project Objectives, NIH 1688-1, September, 2002, 1 page.

#### Business Proposal Forms – (Offeror(s) are to complete and submit with their Business Proposal.)

15. Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours, September, 1992, 2 pages.
16. Contact Points, July, 1991, 1 page.
17. Subcontract Plan Format, March, 2003, 8 pages (*Note: Offeror(s) may complete and submit the attached sample format or their own format which should incorporate the information outlined in FAR 19.704, Subcontracting Plan Requirements.*)
18. Disclosure of Lobbying Activities, OMB Form SF-LLL, December, 1989, 3 pages.
19. Proposal Summary and Data Record, NIH-2043 (Rev. 6/82) , June, 1982, 2 pages.

#### Offeror(s) are to complete and return as soon as possible as indicated on the form.

20. Proposal Intent Response Sheet, March, 1984, 1 page.

## **PART IV - REPRESENTATIONS AND INSTRUCTIONS**

### **SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS**

#### **Representations, Certifications, and Other Statements of Offerors or Quoters (Negotiated).**

##### **1. REPRESENTATIONS AND CERTIFICATIONS.**

The Representations and Certifications required by this particular acquisition can be accessed electronically from the INTERNET at the following URL:

<http://rcb.cancer.gov/rcb-internet/forms/rcneg.pdf>

If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

**IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE THE REPRESENTATIONS AND CERTIFICATIONS AND SUBMIT THEM AS PART OF YOUR BUSINESS PROPOSAL.**



## SECTION L - INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

### **1. GENERAL INFORMATION.**

- a. **INSTRUCTIONS TO OFFERORS-COMPETITIVE ACQUISITION** [FAR Clause 52.215-1 (January 2004)]
- (a) Definitions. As used in this provision-
- "Discussions" are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal. "In writing," "writing," or "written" means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information. "Proposal modification" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award. "Proposal revision" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations. "Time," if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.
- (b) Amendments to solicitations. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).
- (c) Submission, modification, revision, and withdrawal of proposals.
- (1) Unless other methods (e.g., electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.
- (2) The first page of the proposal must show-
- (i) The solicitation number;
  - (ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
  - (iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;
  - (iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and
  - (v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

- (3) Submission, modification, revision, and withdrawal of proposals.
- (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.
  - (ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and-
    - (1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or
    - (2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or
    - (3) It is the only proposal received.
  - (B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.
  - (iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.
  - (iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.
  - (v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.
- (4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.
- (5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.
- (6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.
- (7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.
- (8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

- (d) Offer expiration date. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).
- (e) Restriction on disclosure and use of data. Offerors that include in their proposals data that they do not want disclosed to the public for any purpose, or used by the Government except for evaluation purposes, shall-
  - (1) Mark the title page with the following legend:

This proposal includes data that shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed-in whole or in part-for any purpose other than to evaluate this proposal. If, however, a contract is awarded to this offeror as a result of-or in connection with-the submission of this data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting contract. This restriction does not limit the Government's right to use information contained in this data if it is obtained from another source without restriction. The data subject to this restriction are contained in sheets [insert numbers or other identification of sheets]; and
  - (2) Mark each sheet of data it wishes to restrict with the following legend:

Use or disclosure of data contained on this sheet is subject to the restriction on the title page of this proposal.
- (f) Contract award.
  - (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.
  - (2) The Government may reject any or all proposals if such action is in the Government's interest.
  - (3) The Government may waive informalities and minor irregularities in proposals received.
  - (4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.
  - (5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.
  - (6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.
  - (7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.
  - (8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly

overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

- (9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.
- (10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.
- (11) If a post-award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:
  - (i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.
  - (ii) The overall evaluated cost or price and technical rating of the successful and the debriefed offeror and past performance information on the debriefed offeror.
  - (iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection.
  - (iv) A summary of the rationale for award.
  - (v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.
  - (vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.

(End of provision)

**Alternate I** (Oct 1997). As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

(f)(4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

#### **b. NAICS CODE AND SIZE STANDARD**

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

- (1) The North American Industry Classification System (NAICS) code for this acquisition is 541710.
- (2) The small business size standard is 500 employees.

**THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in EVERY solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.**

**c. TYPE OF CONTRACT AND NUMBER OF AWARD(S)**

It is anticipated that two awards will be made from this solicitation and that the awards will be made on/about May 1, 2005.

It is anticipated that the awards from this solicitation will be multiple-year, completion type, cost reimbursement contracts with a period of performance of 10 years, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

**e. LEVEL OF EFFORT**

It is expected that **completion type contract(s)** will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately as follows for **each** contract:

	Professional Labor Hours	Technical Labor Hours	Total Labor Hours
Base contract -	190,700	528,700	719,400
All Options -	44,975	124,980	169,955

This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

**f. COMMITMENT OF PUBLIC FUNDS**

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

**g. COMMUNICATIONS PRIOR TO CONTRACT AWARD**

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

**h. RELEASE OF INFORMATION**

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

**i. COMPARATIVE IMPORTANCE OF PROPOSALS**

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors are specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

**j. PREPARATION COSTS**

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

**k. SERVICE OF PROTEST (AUGUST 1996) - FAR 52.233-2**

- (a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Contracting Officer  
Research Contracts Branch  
National Institute of Environmental Health Sciences, NIH  
79 T.W. Alexander Drive, 4401 Research Commons Building  
P.O. Box 12874  
Research Triangle Park, North Carolina 27709

- (b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

**l. LATE PROPOSALS AND REVISIONS, HHSAR 352.215-70**

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors-Competitive Acquisition, a proposal received after the date specified for receipt may be considered if it offers significant cost or technical advantages to the Government; and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision)

## **2. INSTRUCTIONS TO OFFERORS**

**a. GENERAL INSTRUCTIONS**

### **INTRODUCTION**

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

**(1) Contract Type and General Clauses**

It is contemplated that a cost-reimbursement level of effort type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

**(2) Authorized Official and Submission of Proposal**

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addresses, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

(a) COVER PAGE

Include RFP title, number, name of organization, identification of the proposal part, and indicate whether the proposal is an original or a copy.

(b) TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

(c) BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

**(3) Proposal Summary and Data Record (NIH-2043)**

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See Section J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD.)

**(4) Separation of Technical and Business Proposals**

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Attachment entitled, TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS). *In the TECHNICAL PROPOSAL SUMMARY OF DIRECT COSTS, labor hours must be broken down sufficiently to allow evaluation of the adequacy of effort proposed for each discipline area to include overall labor classification (professional or technical), labor category (i.e., specific function), individual, and labor hours.* However, the technical proposal should **not** include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

**(5) Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

**(6) Evaluation of Proposals**

The Government will evaluate technical proposals in accordance with the criteria set forth in Part IV, Section M of this RFP.

**(7) Potential Award Without Discussions**

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

**(8) Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurement, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

**Hard Metric** - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

**Soft Metric** - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

**Dual Systems** - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

**(9) Care of Live Vertebrate Animals**

- a. The following notice is applicable when contract performance is expected to involve care of live vertebrate animals:

**Notice to Offerors of Requirement for Adequate Assurance of Protection of Vertebrate Animal Subjects - (SEPTEMBER 1985)**

The Public Health Service (PHS) Policy on Human Care and Use of Laboratory Animals establishes a number of requirements for research activities involving animals. Before a PHS award may be made to an applicant organization, the organization shall file, with the Office of Extramural Research (OER), Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), PHS, a written Animal Welfare Assurance which



commits the organization to comply with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources. In accordance with the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, applicant organizations must establish a committee, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. No PHS award involving the use of animals shall be made unless the Animal Welfare Assurance has been approved by OER, OLAW. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Animal Welfare Assurance is required. The Contracting Officer will request that OER, OLAW negotiate an acceptable Animal Welfare Assurance with those Contractor(s). For further information, OER, OLAW, may be contacted at Rockledge Center I - Suite 1050, 6705 Rockledge Drive, Bethesda, MD 20817, (301) 496-7163, ext 234. FAX copies are of the PHS Policy are available at (301) 402-2803. This policy is also available on the internet at <http://www.grants.nih.gov/grants/olaw/olaw.htm>.

b. The following information must be included in the offerors technical proposal:

- identification of the species and approximate number of animals to be used;
- rationale for involving animals, and for the appropriateness of the species and numbers used;
- a complete description of the proposed use of the animals;
- a description of procedures designed to assure that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research, and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals; and
- a description of any euthanasia method to be used.

c. If an Animal Assurance is already in place, the offeror's proposal shall include:

- The Animal Welfare Assurance number.
- The date last certified by OLAW. (i.e. assurance letter from OLAW)
- Evidence of recent AAALAC Accreditation.

#### **(10) Obtaining and Disseminating Biomedical Research Resources**

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a conditions of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

This policy, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090]) will be included in any contract awarded from this solicitation. It can be found at the following website: <http://ott.od.nih.gov/NewPages/64FR72090.pdf>.

#### **(11) Sharing Research Data**

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data. Therefore, the offeror must submit a plan for data sharing or state why data sharing is not possible. If data sharing is limited, the offeror should explain such limitations in its data sharing plan. NIH's data sharing policy may be found at the following Web site:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>

If the resultant contract is part of a collaborative program involving multiple sites, the data sharing will be governed by a dissemination plan to be developed jointly following award. Offerors must include in their proposals a statement of willingness to work collaboratively after award with the other funded sites to prepare a joint dissemination plan. Coordinating Center proposals should describe methods to coordinate the dissemination planning and implementation. The Coordinating Center must include a budget and justification for any additional costs of this collaborative effort.

#### **(12) Selection of Offerors**

- a) The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.
- b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.
- c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.
- d) If the Government intends to conduct discussions prior to awarding a contract-

- (1) Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

- (2) The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is the NIEHS policy to conduct discussions with all offerors in the competitive range, NIEHS reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR 315.370.

- e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.
- f) The NIEHS reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet NIEHS requirements. Synopses of awards exceeding \$25,000 will be published in the FedBizOpps.

### **(13) Small Business Subcontracting Plan**

If the proposed contract exceeds a total estimated cost of \$500,000 for the entire period of performance, the apparent successful offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, an Attachment to this RFP is an example of such a plan.

- a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.
- b) The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

c) The offeror understands that:

- (1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.
- (2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HubZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.
- (3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.
- (4) Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.
- (5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HubZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.
- (6) The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d) Each plan must contain the following:

- (1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.
- (2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
- (3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and/or Service Disabled Veteran-Owned Small Business Concerns.
- (4) A description of the method used to develop the subcontracting goals.

- (5) A description of the method used to identify potential sources for solicitation purposes.
- (6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
- (7) The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.
- (8) A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.
- (9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of \$500,000 adopt a plan similar to the plan agreed upon by the offeror.
- (10) Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.
- (11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them. For additional information about each of the above elements required to be contained the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an attachment to this RFP in SECTION J.

HHS expects each procuring activity to establish minimum subcontracting goals for all procurements. The anticipated minimum goals for this RFP are as follows: 30.32% for Small Business; 11.12% for Small Disadvantaged Business; 5.05% for Women-Owned Small Business; 3.03% for HUBZone Small Business; 5.56% for 8(a) Business; and, 3% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

**(14) HUBZone Small Business Concerns**

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at <http://www.sba.gov/hubzone>.

**(15) Extent of Small Disadvantaged Business Participation**

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed \$500,000 (\$1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b)). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled “Extent of Small Disadvantaged Business Participation” as set forth under the Evaluation Criteria in Section M shall be used for evaluation purposes.

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) code, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at <http://www.sba.gov/size>

The Department of Commerce website for the annual determination is:  
<http://www.arnet.gov/References/sdbadjustments.htm> .

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Subsector(s). The applicable authorized NAICS Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the prime contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute** for submission of the subcontracting plan, if it is required by this solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

#### EXAMPLE

##### Targets for SDB Participation - NAICS Subsector 223

	SDB Percentage of Total Contract Value	SDB Dollars
Total Contract Value- \$1,000,000	25%	\$250,000
SDB Participation by Prime (Includes joint venture partners and team arrangements)*	10%	\$100,000
SDB Participation by subcontractors	15%	\$150,000

\*Note: FAR Subpart 9.6 defines “Contractor team arrangements” to include two or more companies forming a partnership or joint venture to act as a potential prime contractor, or a potential prime contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

- (16) **Reimbursement of Costs for Independent Research and Development Projects (Commercial Organizations Only)** Reimbursement of Costs for Independent Research and Development Projects (Commercial Organizations Only)

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. This support is provided in the form of contracts and grants totaling approximately 7 billion dollars annually. PHS has established effective, time tested and well recognized and accepted procedures for stimulating and supporting this independent research by selecting from multitudes of proposals those research projects most worthy of support within the constraints of its appropriations. The reimbursement of independent research and development costs not incidental to product improvement, through the indirect cost mechanism, would circumvent this competitive process.

To ensure that all research and development projects receive similar and equal consideration, all offerors may compete for direct funding for independent research and development projects they consider worthy of support by submitting those projects to the appropriate Public Health Service grant and/or contract office for review. Since these projects may be submitted for direct funding, the successful offeror agrees that no costs for any independent research and development project, including applicable indirect costs, will be claimed under any contract resulting from this solicitation.

#### **(17) Salary Rate Limitation in Fiscal Year 2004**

Offerors are advised that pursuant to P.L. 108-199, no NIH Fiscal Year 2004 (October 1, 2003 - September 30, 2004) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I\* (direct salary is exclusive of Overhead, Fringe Benefits, and General and Administrative expenses (also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I\*. The salary rate limitation set by P.L. 108-199 applies only to Fiscal Year 2004 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I\* annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 108-199 states in pertinent part:

"None of the funds appropriated in this Act for the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or extramural mechanism at a rate in excess of Executive Level I.\*"

**\*LINK TO EXECUTIVE SCHEDULE SALARIES:**

<http://www.opm.gov/oca/PAYRATES/index.htm>

**NOTE:** Pertinent information for FY2005 will be added to any contract(s) awarded as a result of this solicitation.

#### **(18) Institutional Responsibility Regarding Conflicting Interests of Investigators**

**EACH INSTITUTION MUST:**

- (a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.
- (b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.
- (c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.
- (d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.
- (e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.
- (f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.
- (g) Certify, in each application/proposal for funding to which the regulations applies, that:
  - 1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;
  - 2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;
  - 3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and



- 4) the Institution will otherwise comply with the regulations.

#### **Institutional Management of Conflicting Interests**

- (a) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.**

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

- (i) public disclosure of significant financial interests;
  - (ii) monitoring of research by independent reviewers;
  - (iii) modification of the research plan;
  - (iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
  - (v) divestiture of significant financial interests; or
  - (vi) severance of relationships that create actual or potential conflicts of interests.
- (b) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

#### **(19) ROTC Access and Federal Military Recruiting on Campus**

Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless of when implemented ) that either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

Further, contract funds may not be provided to educational institutions that have a policy or practice that prohibits or prevents (1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or (2) access by military recruiters for purposes of Federal military recruiting to information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity.

#### **(20) Past Performance Information**

- a) Offerors shall submit the following information as part of their business proposal.

A list of the last five contracts completed during the past three years and all contracts currently in process that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors that are newly formed entities without prior contracts should list contracts and subcontracts as required above for all key personnel.

Include the following information for each contract or subcontract:

1. Name of Contracting Organization

2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. Standard Industrial Code

The offeror shall submit comparable information on all subcontractors that the offeror proposes to perform a major subcontract under this effort. For the purpose of this solicitation, a "major subcontract" is defined as one that exceeds \$500,000.

The offeror may provide information on problems encountered on the identified contracts and the offeror's corrective actions.

- b) Each offeror will be evaluated on its performance under existing and prior contracts for similar products or services. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

**(21) Solicitation Provisions Incorporated by Reference, Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)**

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: <http://www.arnet.gov/far/>.

The following provisions are applicable to this solicitation.

**Submission of Offers in the English Language**, FAR Clause 52.214-34, (April 1991).

**Submission of Offers in U.S. Currency**, FAR Clause 52.214-35, (April 1991).

**Facilities Capital Cost of Money**, FAR Clause 52.215-16, (October 1997).

**Order of Precedence-Uniform Contract Format**, FAR Clause 52.215-8, (October 1997).

**Preaward On-Site Equal Opportunity Compliance Evaluation**, (Over \$10,000,000), FAR Clause 52.222-24, (February 1999).

**Notice of Requirement for Affirmative Action to Ensure Equal Employment Opportunity for Construction**, FAR 52.222-23, (February 1999).

**Preparation of Proposals-Construction**, FAR Clause 52.236-28, (October 1997).

**b. TECHNICAL PROPOSAL INSTRUCTIONS**

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

(1) **Technical Discussions**

The technical discussion included in the technical proposal should respond to the items set forth below:

a) **Project Objectives, NIH-1688-1**

The offeror shall insert a completed NIH Form 1688-1, Project Objective, as provided in Section J, Attachments, behind the Title Page of each copy of the proposal, along with the "Government Notice for Handling Proposals." The NIH Form 1688-1 is to be completed as follows:

- For an **Institution of Higher Education**: The form MUST be completed in its entirety.
- For **OTHER** than an Institution of Higher Education: The starred items (Department, Service, Laboratory or Equivalent, and Major Subdivision) should be left blank.

The information required under the "Summary of Objectives" portion of the form MUST meet the requirements set forth in the section of the form entitled, "**INSTRUCTIONS:**"

b) **Statement of Work**

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

c) **Personnel**

**Offerors are advised that core staff involved in toxicologic research must be in place by the date of proposal submission. The Principal Investigator, Toxicologist, Chemist, Veterinarian, Health and Safety Officer, and Quality Assurance Unit Officer shall be**

**employees of the contract laboratory (i.e., not consultants or subcontractors). The daily interaction and constant coordination of efforts needed amongst these discipline areas throughout the in-life portion of the studies makes it critical that they be physically and organizationally together.**

Offerors should describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. **Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program and the percentage committed to other projects.**

**OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.**

(1) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

(2) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

- The specific items or expertise they will provide.
- Their availability to the project and the amount of time anticipated.
- Willingness to act as a consultant.

-How rights to publications and patents will be handled.

(4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

(d) Summary of Related Activities

The offeror shall complete and include as part of their Technical Proposal the Summary of Related Activities, March 1984, provided in Section J, Attachments.

(e) Facilities

OFFERORS ARE ADVISED THAT IF THEY WISH TO RECEIVE AN AWARD THEY SHALL HAVE A WORKING LABORATORY CONDUCTING STUDIES VIA THE ROUTES OF ADMINISTRATION IDENTIFIED IN ATTACHMENT 1, THE STATEMENT OF WORK IN PLACE BY THE DATE OF PROPOSAL SUBMISSION. A WORKING LABORATORY MEANS THAT THE FACILITY HAS IN PLACE ESSENTIAL FEATURES NECESSARY TO CONDUCT GLP TOXICITY/CARCINOGENICITY STUDIES OF ENVIRONMENTAL AGENTS INVOLVING LARGE GROUPS OF RATS AND MICE (E.G. ENVIRONMENTALLY CONTROLLED ANIMAL ROOMS, ANALYTICAL LABORATORIES, CLINICAL LABORATORY, NECROPSY ROOM, HISTOLOGY FACILITY, ETC.) AND STAFF WITH APPROPRIATE EXPERTISE TO EXPOSE, CARE FOR AND PROCESS LARGE NUMBERS OF ANIMALS (E.G. CHEMISTS, TOXICOLOGISTS, PATHOLOGISTS, CLINICAL PATHOLOGIST, VETERINARIAN, ANIMAL CARE TECHNICIANS, PROSECTORS, HISTOLOGISTS, QUALITY ASSESSMENT GROUP, ETC.). SPECIFICATIONS FOR PERSONNEL ARE SET FORTH IN SECTION I.C. AND FACILITIES ARE SET FORTH IN SECTION II.A. OF ATTACHMENT 2.

LABORATORY EQUIPMENT AND FACILITIES SHALL BE FURNISHED BY THE CONTRACT LABORATORY AS SPECIFIED IN ATTACHMENT 2, SPECIFICATIONS FOR THE CONDUCT OF STUDIES TO EVALUATE THE TOXIC AND CARCINOGENIC POTENTIAL OF CHEMICAL, BIOLOGICAL, AND PHYSICAL AGENTS IN LABORATORY ANIMALS FOR THE NATIONAL TOXICOLOGY PROGRAM (NTP). SPECIFIC DETAILS ARE FOUND IN ATTACHMENT 2.

Offerors should submit a floor plan of the space available for all aspects of the work to be performed. Include evidence to indicate that the facilities will permit performance of the work at the proposed capacity and within the indicated time restrictions. Indicate work areas and equipment to be provided exclusively for this project as well as areas to be shared with other projects.

(2) **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria (located in Section M, hereof).

(3) **Additional Technical Proposal Information**

- a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an

explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

- b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

(4) **Other Considerations**

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

- a. Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship. **Note that the following individuals must be prime contract employees not subcontractor(s) or consultant(s): The Principal Investigator, Toxicologist, Chemist, Veterinarian, Health and Safety Officer, and Quality Assurance Unit Officer.**
- b. Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.
- c. Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.
- d. Other factors you feel are important and support your proposed research.
- e. Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

(5) **Information Technology Systems Security**

(a) **Sensitivity and Security Level Designations.**

The Statement of Work (SOW) requires the successful offeror to develop or access a Federal Automated Information System (AIS). Based upon the security guidelines contained in the *Department of Health and Human Services (DHHS) Automated Information Systems Security Program (AISSP) Handbook*, the Government has determined that the following apply:

(1) Category of Safeguarded Information

The safeguarded agency information that the successful offeror will develop or access is categorized as:

☒ Non Sensitive Information  
☐ Sensitive Information  
☐ Classified Information:  
☐ Confidential ☐ Secret ☐ Top Secret ☐ Special Access

(2) Security Level Designations

<http://www.cit.nih.gov/security-policies.html>

The information that the successful offeror will develop or access is designated as follows:

**Level 1** applies to the sensitivity of the data.

**Level 1** applies to the operational criticality of the data.

The overall Security Level designation for this requirement is **Level 1**.

(3) Position Sensitivity Designations

Prior to award, the Government will determine the position sensitivity designation for each contractor employee that the successful offeror proposes to work under the contract. For proposal preparation purposes, the following designations apply:

[ ] **Level 6C: Sensitive - High Risk (Requires Suitability Determination with a BI).**

Contractor employees assigned to a Level 6C position are subject to a Background Investigation (BI).

[ ] **Level 5C: Sensitive - Moderate Risk (Requires Suitability Determination with NACIC).**

Contractor employees assigned to a Level 5C position with no previous investigation and approval shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), or possibly a Limited Background Investigation (LBI).

[ ] **Level 4C: Classified (Requires Special Access Clearance with an SSBI).**

Contractor employees assigned to a Level 4C position are subject to a Single Scope Background Investigation (SSBI).

[ ] **Level 3C: Classified (Requires Top Secret Clearance with an SSBI).**

Contractor employees assigned to a Level 3C position are subject to a Single Scope Background Investigation (SSBI).

[ ] **Level 2C: Classified (Requires Confidential or Secret Clearance with an LBI).**

Contractor employees assigned to a Level 2C position shall undergo a Limited Background Investigation (LBI).

[ X ] **Level 1C: Non Sensitive (Requires Suitability Determination with an NACI).**

Contractor employees assigned to a Level 1C position are subject to a National Agency Check and Inquiry Investigation (NACI).

Contractor employees who have met investigative requirements within the past five years may only require an updated or upgraded investigation.

(b) **Information Technology (IT) System Security Program**

The offeror's proposal must:

- (1) Include a detailed outline (commensurate with the size and complexity of the requirements of the SOW) of its present and proposed IT systems security program;
- (2) Demonstrate that it complies with the AISSP security requirements, the Computer Security Act of 1987; Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems;" and the DHHS AISSP Handbook.



At a minimum, the offeror's proposed information technology systems security program must address the minimum requirements of a **Security Level \*** identified in the DHHS AISSP Handbook, [Exhibit III-A, Matrix of Minimum Security Safeguards](#).

- (3) Include an acknowledgment of its understanding of the security requirements.
- (4) Provide similar information for any proposed subcontractor developing or accessing an AIS

(c) **Required Training for IT Systems Security**

DHHS policy requires that contractors receive security training commensurate with their responsibilities for performing work under the terms and conditions of their contractual agreements.

The successful offeror will be responsible for assuring that each contractor employee has completed the following NIH Computer Security Awareness Training course prior to performing any contract work: <http://irtsectraining.nih.gov/>. The contractor will be required to maintain a listing of all individuals who have completed this training and submit this listing to the Government.

Additional security training requirements commensurate with the position may be required as defined in OMB Circular A-130 or NIST Special Publication 800-16, "Information Technology Security Training Requirements." These documents provide information about IT security training that may be useful to potential offerors.

(d) **References**

The following documents are electronically accessible:

- (1) OMB Circular A-130, Appendix III: <http://csrc.ncsl.nist.gov/secplcy/a130app3.txt>
- (2) DHHS AISSP Handbook: <http://irm.cit.nih.gov/policy/aissp.html>
- (3) DHHS Personnel Security/Suitability Handbook:  
<http://www.hhs.gov/ohr/manual/pssh.pdf>
- (4) NIH Applications/Systems Security Template:  
<http://cit.nih.gov/security/secplantemp.html>
- (5) NIST Special Publication 800-16, "Information Technology Security Training Requirements:" <http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf>
- (6) NIH CIT-Policies, Guidelines and Regulations:  
Table 1 - Categories of Safeguarded Agency Information:  
<http://irm.cit.nih.gov/security/table1.htm>

Table 2 - Security Level Designations for Agency Information:  
<http://irm.cit.nih.gov/security/table2.htm>

Table 3 - Positions Sensitivity Designations for Individuals Accessing Agency Information: <http://irm.cit.nih.gov/security/table3.htm>

c. **BUSINESS PROPOSAL INSTRUCTIONS**

1. **Basic Cost/Price Information**

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor,

fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

## **2. Proposal Cover Sheet**

The following information shall be provided on the first page of your pricing proposal:

- a. Solicitation, contract, and/or modification number;
- b. Name and address of Offeror;
- c. Name and telephone number of point of contact;
- d. Name, address, and telephone number of Contract Administration Office, (if available);
- e. Name, address, and telephone number of Audit Office (if available);
- f. Proposed cost and/or price; profit or fee (as applicable); and total;
- g. The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.
- h. Date of submission; and
- i. Name, title and signature of authorized representative.

This cover sheet information is for use by offerors to submit information to the Government when cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not considered cost or pricing data, and shall not be certified in accordance with FAR 15.406-2.

## **3. Cost and Pricing Data**

### **a. General Instructions**

(1) You must provide the following information on the first page of your pricing proposal:

- (a) Solicitation, contract, and/or modification number;
- (b) Name and address of offeror;
- (c) Name and telephone number of point of contact;
- (d) Name of contract administration office (if available);
- (e) Type of contract action (that is, new contract, change order, price revision/redetermination, letter contract, unpriced order, or other);
- (f) Proposed cost; profit or fee; and total;
- (g) Whether you will require the use of Government property in the performance of the contract, and, if so, what property;
- (h) Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;
- (i) The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR 15.403-5(b)(1) and Table 15-2. By submitting this proposal, we grant the Contracting Officer and authorized representative(s) the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data,

regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price;

- (j) Date of submission; and
- (k) Name, title and signature of authorized representative.

- B. In submitting your proposal, you must include an index, appropriately referenced, of all the cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.
- C. As part of the specific information required, you must submit, with your proposal, cost or pricing data (that is, data that are verifiable and factual and otherwise as defined at FAR 15.401). You must clearly identify on your cover sheet that cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including--
  - (1) The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and
  - (2) The nature and amount of any contingencies included in the proposed price.
- D. You must show the relationship between contract line item prices and the total contract price. You must attach cost-element breakdowns for each proposed line item, using the appropriate format prescribed in the "Formats for Submission of Line Item Summaries" section of this table. You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.
- E. When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost.
- F. Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.
- G. If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.
- H. As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406-2, submit a Certificate of Current Cost or Pricing Data.

## 2. **Cost Elements**

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

- A. **Materials and services.** Provide a consolidated priced summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own cost or pricing data submissions for subcontracts expected to exceed the

appropriate threshold in FAR 15.403-4. Submit the subcontractor cost or pricing data as part of your own cost or pricing data as required in paragraph 2.A(2) of this table. These requirements also apply to all subcontractors if required to submit cost or pricing data.

- (1) *Adequate Price Competition.* Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.403-4 priced on the basis of adequate price competition. For interorganizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR 31.205-26(e)).
  - (2) *All Other.* Obtain cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR 15.403-4 and not otherwise exempt, in accordance with FAR 15.403-1(b) (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the lower of either \$10,000,000 or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor's proposed price. The Contracting Officer may require you to submit cost or pricing data in support of proposals in lower amounts. Subcontractor cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime contractor's Certificate of Current Cost or Pricing Data. The prime contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For interorganizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's cost or pricing data is required as described in this paragraph, it must be included along with your own cost or pricing data submission, as part of your own cost or pricing data. You must also submit any other cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.
- B. **Direct Labor.** Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish bases for estimates.
- C. **Indirect Costs.** Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.
- D. **Other Costs.** List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.
- E. **Royalties.** If royalties exceed \$1,500, you must provide the following information on a separate page for each separate royalty or license fee:

- (1) Name and address of licensor.
- (2) Date of license agreement.
- (3) Patent numbers.
- (4) Patent application serial numbers, or other basis on which the royalty is payable.
- (5) Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
- (6) Percentage or dollar rate of royalty per unit.
- (7) Unit price of contract item.
- (8) Number of units.
- (9) Total dollar amount of royalties.
- (10) If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.204 and 31.205-37).

F. **Facilities Capital Cost of Money.** When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB-CMF and show the calculation of the proposed amount (see FAR 31.205-10)3. **Formats for Submission of Line Item Summaries**

The detailed breakdown shall be in the format as shown on the form **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours** (Section J, List of Attachments). For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished.

4. There is a clear distinction between submitting cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of cost or pricing data is met when all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or by specific identification, to the Contracting Officer or an authorized representative. As later information comes into your possession, it should be submitted promptly to the Contracting Officer in a manner that clearly shows how the information relates to the offeror's price proposal. The requirement for submission of cost or pricing data continues up to the time of agreement on price, or an earlier date agreed upon between the parties if applicable.
  5. By submitting your proposal, you grant the Contracting Officer or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price.
4. **Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data** [FAR Clause 52.215-20 (October 1997)]
- (a) Exceptions from cost or pricing data.
    - (1) In lieu of submitting cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

- (i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.
- (ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include--
  - (A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;
  - (B) For market-priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;
  - (C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.
- (2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.
- (b) Requirements for cost or pricing data. If the offeror is not granted an exception from the requirement to submit cost or pricing data, the following applies:
  - (1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15-2 of FAR 15.408.
  - (2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision)

Alternate I (October 1997). As prescribed in 15.408(l), substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision:

- (b) (1) The offeror shall submit cost or pricing data and supporting attachments in the following format:

The format specified in paragraph L.2.c.(4) Cost and Pricing Data, subparagraph 3. Formats for Submission of Line Item Summaries shall be used for the submission cost information. Submission of all other cost or pricing data shall be in accordance with Table 15-2 in FAR 15.408.

## **5. Total Compensation Plan - Instructions**

- a) Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors [included in the competitive range will be required to/as a part of their business proposal] will submit a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.
- b) The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).
- c) Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror

## **6. Total Compensation Plan - Evaluation**

### **a) Total Compensation Plan (Professional Employees)**

In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

### **b) Cost (Professional Compensation)**

Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

### **c) Other (Labor Relations)**

An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

### **d) Federal Acquisition Regulation Clauses incorporated by Reference**

7. **Qualifications of the Offeror**

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a) **General Experience**

**General experience** is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b) **Organizational Experience Related to the RFP**

**Organizational experience** is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c) **Performance History**

**Performance history** is defined as meeting contract objectives within delivery and cost schedules on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d) **Pertinent Contracts**

**Pertinent contracts** are defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e) **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

8. **Other Administrative Data**

a) **Property**

- (1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned



property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:

- (a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.
- (b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.
- (2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.
- (3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractor's Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

#### **9. Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38, (May 1999)**

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

- (a) The solicitation number (or other procurement identification number).
- (b) The offeror's name and remittance address, as stated in the offer.
- (c) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
- (d) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
- (e) The offeror's account number and the type of account (checking, savings, or lockbox).
- (f) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
- (g) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

#### **10. Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

#### **11. Incremental Funding**

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the

contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

**HHSAR 352.232-75, Incremental Funding (January 2001)**

- (a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.
- (b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions.

(End of provision)

**12. Facilities Capital Cost of Money, FAR 52.215-16, (June 2003)**

(Note: This is applicable if you are a commercial organization.)

- (a) Facilities capital cost of money will be an allowable cost under the contemplated contract, if the criteria for allowability in FAR 31.205-10(b) are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.
- (b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money. (End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

- ☐ The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).
- ☐ The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

**13. Subcontractors**

**Note: The following individuals must be prime contract employees not subcontractor(s) or consultant(s): The Principal Investigator, Toxicologist, Chemist, Veterinarian, Health and Safety Officer, and Quality Assurance Unit Officer.**

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

- a) Willingness to perform as a subcontractor for specific duties (list duties).
- b) What priority the work will be given and how it will relate to other work.

- c) The amount of time and facilities available to this project.
- d) Information on their cognizant field audit offices.
- e) How rights to publications and patents are to be handled.
- f) A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

<http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm>

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

#### **14. Representations and Certifications**

One copy of the Representations and Certifications attached as Section K shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor.

#### **15. Travel Costs/Travel Policy**

(Note: This is applicable if you are a commercial organization.)

##### **a) Travel Costs - Commercial**

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

##### **b) Travel Policy**

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

#### **16. Certification of Visas for Non-U.S. Citizens**

Proposed personnel under research projects are not required to be citizens of the United States. However, if non-U.S. citizens are proposed under a contract to be performed in the United States and its outlying areas, then the offeror must indicate in the proposal that these individuals have the required visas.

#### **17. Proposer's Annual Financial Report**

A copy of the organization's most recent annual report must be submitted as part of the business

proposal.

**18. Instructions for Submission of Separate Itemized Cost Breakdowns in the Business Proposal**

Four Sample Work Assignments (A, B, C, and D) have been included in Attachment 1, the Statement of work, in order to provide offerors some examples of study designs that might be conducted under this contract. Offerors are to provide technical and cost information in their proposal for each of the Sample Work Assignments and costs for an Administrative Work Assignment for time and expenditures associated with administration of the contract.

For estimating the total effort over the 10-year period of this contract, offerors are to assume Work Assignments according to APPENDIX E: Schedule for Work Assignments of Attachment 1, the Statement of Work. An optional Work Assignment may be issued each year. For costing purposes, offerors are to assume the study type (13-week and 104-week gavage) and the schedule provided in APPENDIX F: Schedule for Optional Work Assignments of Attachment 1, the Statement of Work.

**Offerors are to submit detailed itemized cost breakdowns by cost element (to include a detailed breakdown of direct labor (i.e., to include labor classification (category and professional or technical), individual, labor hours, labor rates, extended totals) with the period of performance for the following:**

**Base Contract**

- (1) for each study (i.e., prestart effort, 14-day, 13-week, or 2-year study) within a Work Assignment and for each Work Assignment in the base contract (i.e., Work Assignments 1, 2, 3, 5, 6, 7, 8, 10, 11, 12, 13, 15, 16, 17, 18, 20, 21, 22, 23, 25, 26, 27, 28) to include an Administrative Work Assignment (reference Appendix E) with a total of all work assignments for the base contract.**
- (2) by contract year (2005 through 2015) for incremental funding purposes.**

**Options**

- (1) for Work Assignments 4, 9, 14, 19, 24, and 29 to include a separate breakdown of each study (i.e., prestart effort, 13-week and 2-year study) within the Work Assignment with a total for the Work Assignment (reference Appendix F for optional Work Assignments).**
- (2) for the increase in the Administrative Work Assignment associated with the exercise of each option period.**
- (3) a total for all options.**

## **SECTION M - EVALUATION FACTORS FOR AWARD**

### **a. GENERAL**

Selection of an offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: technical, cost, past performance and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, past performance, cost/price and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below. The offeror must clearly define how any proposed subcontract/consultant arrangements would meet program needs.

The Offeror is to submit the following items as part of their technical proposal:

- A functional organization chart for the project
- The Organization's Quality Management Plan
- Facility floor plans to include airflow direction and traffic flow of personnel and equipment through the facility proposed for use on these studies. All rooms are to be labeled as to use.
- A brief overview to demonstrate an understanding of the test chemicals (in the Sample Work Assignments), potential biological effects, and how this information relates to study design.
- A milestone schedule for the Sample Work Assignments provided, including separate dates for sexes if staggered, and all reports/deliverables.
- A table listing all chemistry activities and the number of times each of those activities will be performed throughout the course of the project for each Sample Work Assignment.
- Health and Safety Chemical Hygiene Plan (A General Facility Plan).
- A list of Standard Operating Procedures (SOPs) to be used in the management and technical conduct of these studies.
- Relevant clinical pathology historical control data for all parameters required in the Sample Work Assignments.

### **b. MANDATORY QUALIFICATION CRITERIA**

Listed below are mandatory qualification criteria. The offeror shall include all information which documents and/or supports the qualification criteria in one clearly marked section of its proposal. The offeror shall provide an index within its proposal which directs the reviewer(s) to the specific area(s) of the proposal that address a particular mandatory qualification.

The qualification criteria establishes conditions that must be met at the time of receipt of proposal(s) by the Contracting Officer in order for your proposal to be considered any further for award.

**The Offeror shall have a working laboratory conducting studies via the routes of administration identified in Attachment 1, the Statement of Work, in place by the date of proposal submission. The Principal Investigator, Toxicologist, Chemist, Veterinarian, Health and Safety Officer, and Quality Assurance Unit Officer shall be employees of the contract laboratory (i.e., not consultants or subcontractors). The daily interaction and constant coordination of efforts needed amongst these**

discipline areas throughout the in-life portion of the studies makes it critical that they be physically and organizationally together.

A working laboratory means that the facility has in place essential features necessary to conduct GLP toxicity/carcinogenicity studies of environmental agents involving large groups of rats and mice (e.. environmentally controlled animal rooms, analytical laboratories, clinical laboratory, necropsy room, histology facility, etc) and staff with appropriate expertise to expose, care for, and process large numbers of animals (e.g., chemists, toxicologists, pathologists, clinical pathologist, veterinarian, animal care technicians, prosectors, histologists, quality assessment group, etc.). Specifications for personnel and facilities are set forth in Attachment 2, the NTP Specifications.

**c. EVALUATION OF OPTIONS**

It is anticipated that any contract(s) awarded from this solicitation will contain option provision(s) and period(s).

In accordance with FAR Clause 52.217-5, Evaluation of Options, (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the option(s).

**d. EVALUATION OF DATA SHARING PLAN**

The offeror's plan for the sharing of final research data, or, if data sharing is not possible, the offeror's documentation of its inability to share research data, shall be assessed for appropriateness and adequacy.

**e. TECHNICAL EVALUATION CRITERIA**

The technical proposal will receive paramount consideration. The evaluation will be based on the demonstrated capabilities of the contractor in relation to the needs of the project as set forth in the RFP. The merits of the proposal will be evaluated carefully. The offeror must submit information sufficient to evaluate their proposal based on responsiveness to the RFP and the criteria listed below. These evaluation criteria will be used by the technical evaluation committee to evaluate the technical proposal. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

Technical Evaluation Criteria [MAXIMUM POINTS = 1000]

**1. Study Management and Coordination (170 points)**

(100) Adequacy of proposed approach to project management, including a functional organization chart, Quality Management Plan, and experience relative to the project team; details of project scheduling and monitoring of progress, steps to encourage communication amongst project staff, and financial monitoring; adequacy of the proposed schedule for each Task within the project, including specific dates for all milestones and deliverables; if subcontracts/consultants are proposed, details for coordinating those efforts.

(70) Training and experience of Principal Investigator in the conduct of toxicologic studies and in the management and coordination of multidisciplinary projects, including adequacy of the discussion of specific duties and responsibilities, and availability to the project; experience and training of the proposed data management staff (including TDMS and non-TDMS data); proposed procedures for day-to-day data management including, collection, coordination, review for completeness and accuracy, archiving and submission to NTP; discussion of specific

duties and proposed effort on the project.

2. Performance of Analytical Chemistry (150 points)

- (90) Adequacy of the detailed discussion of the proposed approach for bulk chemical reanalysis, dose formulation and dose analysis, including a discussion of any special considerations or potential problem areas regarding the specific test chemicals; adequacy of the proposed table listing all chemistry activities indicating the timing of these activities and the total number of times each activity will be performed throughout the course of the project.
- (60) Experience and training of the proposed Chemist and chemistry technicians, including experience and training of the chemistry staff; adequacy of the discussion of specific duties, and proposed effort on the project; and adequacy and appropriateness of facility and equipment for chemistry aspects.

3. Conduct of Toxicology Aspects (150 points)

- (90) Demonstrated understanding of the specific test agents and their biological effects, and how this information relates to study design and possible results; adequacy of the proposed approach for collection, review and quality control of in-life data.
- (60) Experience and training of the proposed Toxicologist and toxicology technicians, including adequacy of the discussion of specific duties, and proposed effort on the project; experience with all required routes of exposure of rodents and with long-term (2-year) studies; recent relevant gavage proficiency data; experience with perinatal exposure; experience conducting and interpreting results of special studies (P450, alpha-2 $\mu$ -globulin, glutathione, FOB, teratology, etc.).

4. Conduct of Pathology Aspects (150 points)

- (90) Experience and adequacy of the discussion of the proposed approach and procedures for conduct of pathology, including specific experience with rodents, and specific details of procedures to assure accuracy and quality; specific experience with cell proliferation (PCNA and BrdU).
- (60) Experience and training of the proposed Pathologist(s), prosectors, histology technicians, including adequacy of the discussion of specific duties, and proposed effort on the project; adequacy and appropriateness of facility and equipment for pathology aspects.

5. Performance of Laboratory Animal Management (150 points)

- (90) Adequacy of the discussion of the proposed approach and procedures for laboratory animal management, including specific experience with rodents; experience with transgenic models; experience with dosed feed, dosed water, dermal and gavage studies.
- (60) Experience and training of the proposed Veterinarian and animal care technicians, including adequacy of the discussion of specific duties, and proposed effort on the project; adequacy and appropriateness of facility and equipment for lab animal management, including detailed floor plans.

6. GLP Compliance and Quality Assurance (90 points)

- (50) Adequacy of the submitted documentation of compliance with GLP requirements and

discussion of the proposed approach and procedures for quality assurance, including details of the operating procedures of the Quality Assurance Unit.

- (40) Experience and training of the proposed Quality Assurance Officer and support staff, including adequacy of the discussion of specific duties, and proposed effort on the project; adequacy and appropriateness of facility dedicated to quality assurance efforts.

7. Performance of Clinical Pathology Studies (90 points)

- (50) Proposed approach for conducting clinical pathology studies, including historic control, proficiency and quality control data; detailed discussion of the proposed approach and methods for hematology, clinical chemistries, urinalysis, thyroid hormones, etc.
- (40) Experience and training of the proposed professional and technical staff to conduct the clinical pathology studies; including adequacy of the discussion of specific duties, and proposed effort on the project; adequacy and appropriateness of facility and equipment for the conduct of these studies.

8. Health and Safety Aspects (50 points)

- (25) Adequacy of the discussion of the proposed approach and procedures for health and safety aspects addressing the specific test agents, including personal protection procedures/equipment, and monitoring methods and strategy; adequacy of the Health and Safety Chemical Hygiene Plan.
- (25) Experience in supporting toxicity studies and training of the proposed Health and Safety Officer and any support staff, including adequacy of the discussion of specific duties, and proposed effort on the project; adequacy and appropriateness of facility and equipment for health and safety aspects, including floor plans, airflows.

**f. PAST PERFORMANCE FACTOR**

An evaluation of offerors' past performance information will be conducted prior to any communications with offerors leading to establishment of the competitive range. However, this evaluation will not be conducted on any offeror whose proposal will not be admitted to the competitive range on the basis of the results of the evaluation of factors other than past performance.

The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be a product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgement by the Government after it considers relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and



forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

**g. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION**

**SDB participation will not be scored**, but the Government's conclusions about overall commitment and realism of the offeror's SDB Participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

- (a) Extent to which SDB concerns are specifically identified
- (b) Extent of commitment to use SDB concerns
- (c) Complexity and variety of the work SDB concerns are to perform
- (d) Realism of the proposal
- (e) Past performance of offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation
- (f) Extent of participation of SDB concerns in terms of the value of the total acquisition.